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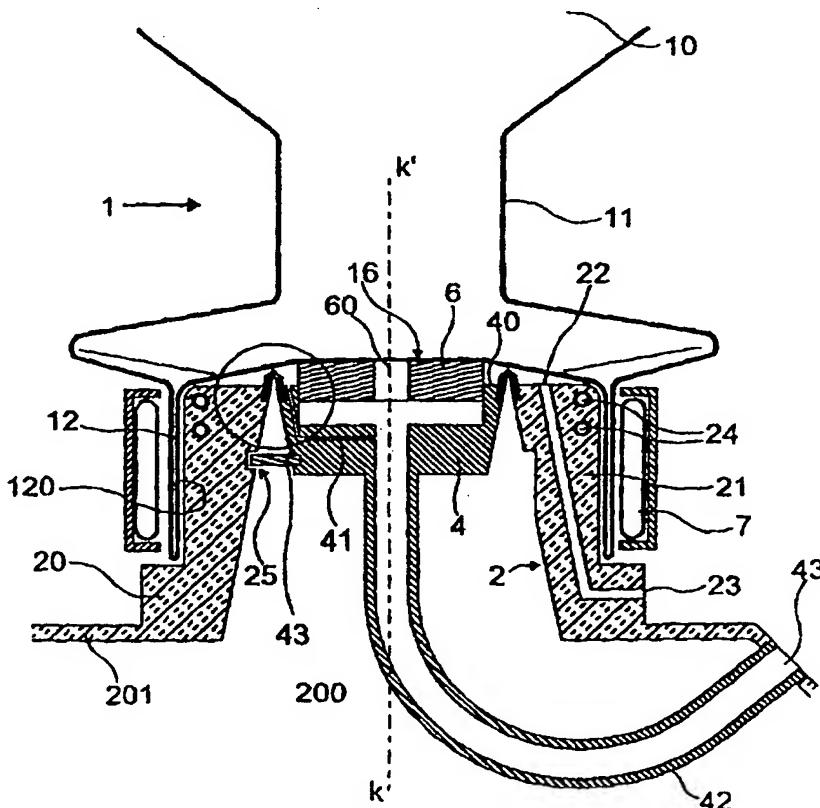
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<b>(21) International Application Number:</b> PCT/EP96/05117 <b>(22) International Filing Date:</b> 20 November 1996 (20.11.96) <b>(30) Priority Data:</b> 95/14054                      22 November 1995 (22.11.95)      FR <b>(71) Applicant (for all designated States except US):</b> LABORATOIRES MERCK SHARP & DOHME - CHIBRET SNC [FR/FR]; 3, avenue Hoche, F-75008 Paris (FR). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> LATAIX, Gilbert [FR/FR]; 44, avenue Edouard-Michelin, F-63100 Clermont-Ferrand (FR). WICKY, Charles [FR/FR]; 3c, rue des Tuiles, F-68500 Jungholtz (FR). <b>(74) Agent:</b> HISCOCK, Ian, James; Merck & Co., Inc., European Patent Dept., Terlings Park, Eastwick Road, Harlow, Essex CM20 2QR (GB).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BI, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

**(54) Title:** TRANSFER SYSTEM BETWEEN A BAG AND A STERILE ENCLOSURE**(57) Abstract**

The system comprises on the one hand a bag (1) presenting a mouth (120) in the form of a pocket, in which the bottom is constituted by a flexible partition (16) separating the interior spaces of the pocket and the bag and capable of being heat-cut, on the other hand a lock chamber installed at the entrance to the sterile enclosure (200) which includes a fixed part (2) on which the pocket can be mounted (120), this part (2) presenting a central opening receiving a mobile element (4) constituting the door of the lock chamber, the fixed (2) and mobile (4) parts each being equipped with a heatable blade (3, 5) with closed outline overlapping and joined at their apex in airtight manner when the bag is in the closed state, vacuum outlets being provided for applying the flexible partition (16) by means of suction against the heatable blades (3, 5) and effecting the cutting of it by fusion of the zones which come into contact with the blades. Possible application notably in the pharmaceutical, cosmetic industry and in the medical field.



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## TRANSFER SYSTEM BETWEEN A BAG AND A STERILE ENCLOSURE

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This invention concerns a transfer system, guaranteed sterile, between a bag and a sterile enclosure, by means of a cutting transfer lock chamber.

10 This invention is intended particularly, but not exclusively, for the pharmaceutical industry and/or the medical field, for the economic transfer of loose products or liquids or individual sterile articles from a bag to a sterile enclosure or the reverse.

15 The transfer of previously sterilised products contained in a bag (or other container) to a sterile enclosure or zone presents a problem when the said products cannot be autoclaved or heat-sterilised or when they cannot be filtered (in the case of liquids).

The principal methods currently known for carrying out such a transfer are as follows:

20 1) Bags or containers are used which are equipped with special doors such as those marketed by "LA CALHENE", DPTE ("airtight transfer double door"), in accordance with the principle which is the subject of patent FR-A-1 346 486.

25 This method guarantees a sterile transfer; however, it also carries the inconvenience that the doors are expensive and have a limited lifetime; furthermore, the return circulation of the containers equipped with these doors must be managed, which poses practical problems of storage and maintenance.

30 2) Also known is the external sterilisation using a sterilising agent (notably of the paracetic acid +H<sub>2</sub>O<sub>2</sub> type) of bags or containers placed in an entry enclosure, then put in communication with the sterile enclosure once sterilisation of the bags or containers and the entry enclosure has been carried out.

This type of method guarantees a sterile transfer but it is a slow method. In effect, desorption of the sterilisation product must be awaited before carrying out the transfer; in addition, the problem of migration of the sterilising products into the bags or containers must also be taken into account.

5           3) Finally, another known method is the sterilisation of bags or containers together, placed in another bag.

The first bag having been opened on the non-sterile side, the interior bag is transferred into the sterile area through a lock chamber which can be equipped with germicide tubes. This method does not guarantee a strictly sterile transfer. This is why it is mainly used in semi-sterile blocks, in the interior of which  
10           the operating personnel is physically present as, here again, sterility is not guaranteed.

Through document FR-A-2 338 869, a process and an appliance are also known which are supposed to enable the discharge of a sterile receptacle in a  
15           sterile environment.

According to this process, the bottom of the receptacle containing the items to be transferred, such as stacked cups for example, is cut by a knife with a closed outline, on which the cutting edge can have been previously heated

To prevent contamination, before the bottom is cut, it is covered with  
20           an adhesive strip of which the exterior surface, on the side of the sterile enclosure, is also sterile.

In practice, the effectiveness of such a process is problematic, as contaminated particles sandwiched between the bottom of the receptacle and the adhesive, in which airtightness is not monitored at all, are also liable to be  
25           transferred during the operation following cutting.

Furthermore, this process requires the affixing of an adhesive film, the sterility of which is also difficult to monitor and which - in any event - puts a marked strain on the costs of the transfer operation.

This invention has as its objective the resolution of the difficulties  
30           associated with the above-mentioned technique, by offering a system which can provide a guaranteed sterile transfer, particularly suited, although not limited to,

sterile objects and materials, the design of which enables in addition a reduction in the cost both of the operation and of the packaging required, as well as in the time needed for the operation.

These different objectives are achieved by means of the transfer system  
5 which is the subject of the invention, in that:

- a) the bag has at least one mouth in the form of a pocket, in which the bottom is composed of a flexible partition made from material which is capable of being heat-cut by fusion, which separates the interior spaces of the pocket and the bag;
  - 10 b) the entrance to the enclosure is equipped with a lock chamber composed of a fixed exterior part, in the form of a sleeve and an interior mobile part, constituting the door of the lock chamber;
  - c) the fixed and mobile parts are both fitted with a heatable blade with closed outline, one exterior integral to the fixed part and the other interior  
15 integral to the mobile part, these two blades overlapping and being joined at their apex, in an airtight manner, when the lock chamber is in the closed state;
  - d) the lock chamber and the mouth of the bag in the form of a pocket are formed in such a way that it is possible to mount this mouth on the exterior part, the flexible partition then coming into place in relation to the set of  
20 blades (lock chamber closed);
  - e) the lock chamber is equipped with vacuum outlets designed to apply the flexible partition by means of suction against the heatable blades and to effect its cutting by fusion of the areas coming into contact with the blades
- Moreover, in accordance with a certain number of advantageous,  
25 non-limitative characteristics of the invention:
- the said fixed part of the lock chamber has a polygonal-shaped head, hexagonal for example, on which the mouth of the bag is mounted;
  - the system comprises means of holding the mouth of the bag on the fixed part, for example an inflatable sleeve;
  - 30 - vacuum outlets are provided both in the interior and on the exterior of the set of blades and close to them;

- the said blades are metal blades heated electrically, for example by a high frequency current or by Joule effect (heating elements);
- the lock chamber is equipped with the means of cooling the blades;
- 5       - the blades have a circular outline;
- the mobile part of the lock chamber is equipped with a sliding central element, forming a piston, traversed by a vacuum channel and on which the frontal surface is designed to act as support for the central zone of the partition;
- the lock chamber is fitted at the entrance to the enclosure in such
- 10 a way that it can be removed, as an airtight door collar can be fitted there in its place.

The invention also concerns a bag for a transfer system such as mentioned above, this bag being remarkable in that it is made of plastic material and is produced by heat-sealing from a plastic sheath or sheets and presents, when

15 flat a transfer zone presenting a mouth constituted by a folded zone, which can be expanded to form a flat-bottomed pocket adaptable to the lock chamber.

Furthermore, according to a certain number of additional characteristics, non-limitative, of this bag:

- the transfer zone is produced by a seal in the folded zone
- 20 involving a change of direction at an angle greater than or equal to  $30^\circ$  and located at a distance from the fold and short of it which is equal to approximately 0.3 times the width of the opening of the flattened pocket;
- the neck above the transfer zone is shaped in such a way that it can be turned over and threaded onto the fixed part of the lock chamber after opening
- 25 of the lock chamber, to make a funnel and protect the contents of the bag from contact with the exterior blade;
- the bag is shaped in such a way that it is possible to make it temporarily airtight which isolates the interior of the bag from the transfer zone;
- the internal surfaces of the pocket-shaped mouth are protected
- 30 from contamination by at least one airtight seal;
- the bag comprises at least one inflation appendage;

- the bag is provided, at its mouth, with means of gripping, facilitating the expansion to shape of the pocket and its mounting on the lock chamber;

- its mouth is folded double, in such a way as to form a peripheral groove capable of receiving, by means of interlocking, an element for expanding to shape and rigidifying the pocket.

Other characteristics and advantages of the invention will appear from the description and the drawings in annex which show, by way of example of non-limitative embodiment, possible methods of embodiment of it.

In these drawings:

- figure 1 is a perspective diagrammatic view of a flexible bag made of plastic material, a component of the system which is the subject of the invention;

- figure 2 is a diagrammatic view in cross-section of the mouth of the bag, this view being intended to show how the folded zone which forms the mouth pocket from it is constituted;

- figure 3 is a perspective view illustrating the manner in which a plastic sheet intended for making the bag is folded in the mouth area, this view also showing sealing bars and the trace of the seal on the plastic sheet in the mouth area;

- figure 4 is an enlarged partial view of figure 3, showing the fold;

- figure 5 illustrates the dimensioning of the fold and the shape of the seal in that zone;

- figures 6 to 8 are diagrammatic front views of three methods of possible embodiment of the bag, one provided with a lateral transfer zone, the other with an axial transfer zone and the third having a large capacity, all of these bags being shown empty and flat;

- figure 9 is a perspective view of the bag in figure 8, shown filled;

- figure 10 illustrates in perspective the bag transfer zone following the expansion to volume of the pocket-shaped mouth which has a hexagonal shape;

- figure 11 is a perspective view representing the transfer lock chamber which also forms part of the system according to the invention, lock chamber found at the entrance to a sterile enclosure not shown;
- figure 12 is a diagrammatic view in cross-section which shows the  
5 bag mounted on the lock chamber, before the transfer operation;
- figure 13 is an enlarged partial view of figure 12 in the area of the cutting blades;
- figure 14 is a similar view to figure 12, showing the system following cutting of the bag but before transfer;
- 10 - figure 15 is an enlarged view of figure 14 in the area of the cutting blades;
- figure 16 is a similar view to figures 12 and 14 following cutting of the bag, the door of the lock chamber being open and the bag transfer zone turned over, with a view to the transfer of the products from the bag to the sterile  
15 enclosure;
- figures 17 and 18 are enlarged partial views of figure 16, in the area of the exterior blade and of the area of the interior cutting blade respectively;
- figure 19 shows, diagrammatically and in cross section, a transfer system in which the lock chamber is removable, the lock chamber being shown on  
20 an airtight door collar, the bag being reclosed by an additional seal isolating the sterile contents;
- figure 20 is a similar view to figure 19, which shows the sterile enclosure reclosed by its airtight door, the lock chamber reclosed and disconnected, the transfer pocket separated, the rest of the bag being mounted on  
25 an airtight door collar;
- figure 21 is a similar view, showing the bag equipped with its airtight door reconnected to the sterile enclosure;
- figure 22 is a partial diagrammatic view, in perspective, which shows a variant of the transfer pocket which is fitted with additional protective  
30 seals;



- figure 23 shows diagrammatically, in perspective, a variant of the bag, equipped with two transfer pockets and used for emptying a material in sheet form;

5       - figure 24 shows, in perspective, the mouth zone of the bag, following the expansion to volume of the pocket in hexagonal form, this variant of the bag being equipped with means of gripping and of assistance for the expansion to volume;

10       - figure 25 is a partial view of a variant of the bag, from its mouth which is folded double so as to form a peripheral groove capable of receiving by interlocking an element for expanding to shape and rigidifying the pocket;

      - figure 26 is a perspective view of this rigidifying element.

15       The bag 1 shown in figure 1 is a bag with flexible walls, produced from a sheet of plastic material, transparent or non-transparent, which can be heat-cut by fusion, for example polyethylene with a low level of thickness, of the order of 120 micrometres.

      It concerns an airtight envelope, its edges hermetically sealed by a line of heat-sealing 15 which integrates the front and rear surfaces of the envelope.

20       The seal, initially incomplete, is, of course, completed around the entire surrounding edge of the envelope after the products or articles which are to be contained in the bag have been introduced into it; in the drawing, a few articles are shown contained in the bag, using the reference O.

      It concerns sterile products, the bag's interior space also being sterile, either because the filling has taken place in a sterile chamber or because the bag and its contents have been sterilised after filling.

25       Reference 10 has been used to designate the main body of the bag, reference 11 its neck through which the products or articles contained within the body 10 will pass to be transferred into the sterile enclosure, as will be explained below.

30       The neck 11 opens into a mouth zone 12 which, as will also be seen below, affects the form of a pocket in which the open side opens towards the

exterior (towards the bottom of figure 1). At the opposite end (towards the top of the figure), the bag has a bottom 14.

On each side of the mouth 12, the wall of the bag presents free lateral parts 13, separated from the mouth 12 by a line of sealing 15'. As is seen in more detail in figure 2, the mouth zone 12 is folded internally so as to form a pocket 120.

On figure 2, references 121 and 127 have been used to designate the external surfaces of the wall of the bag and references 123, 125, the interior surfaces of the pocket 120, which are connected to surfaces 121, 127 respectively by 180° folds, 122, 126.

The bottom of the pocket corresponds to a fold with the reference 124.

If the pocket 120 is expanded to shape starting from its initial flat configuration as shown in figure 2, to give it a certain volume - as illustrated in figure 1 - the area of the fold 124 will unfold and stretch to form a flat - or approximately flat - partition 16 which constitutes the bottom of the pocket 120 and separates it from the internal volume of the bag.

In the method of embodiment of the lock chamber illustrated in figure 11, which corresponds to a preferred method of embodiment, the lock chamber has a hexagonal outline, with rounded corners, and the configuration of the mouth 12 and the seals 15 is determined in such a way that when the pocket 120 is given the same hexagonal configuration, the partition 16 is more or less flat and level, perpendicular to the longitudinal axis of the bag 1.

These configurations are illustrated in more detail in figures 3 to 5.

In figure 3, references  $X_1$  and  $X_2$  have been used to designate two symmetrical sealing bars, in which the shapes correspond to the outline which is desired for the neck and mouth areas of the bag, by heat-sealing

Varied fine dashes and the references  $x_1$  and  $x_2$  have been used to indicate the outline projections of bars  $X_1$  and  $X_2$ , respectively, on the sheath of plastic material from which the bag is to be manufactured, a sheath only partially shown in the diagram. References 100 and 106 have been used to designate the

front and rear surfaces of the sheath, references 102 and 104 the surfaces of the area folded internally (surfaces which correspond - at the pocket - to surfaces 123 and 125 mentioned above).

References 101 and 105 have been used to designate the folds which link surfaces 100 and 102 on the one hand and 104 and 105 on the other, respectively; finally, reference 103 has been used to designate the interior fold (which corresponds to the pocket fold 124 mentioned above).

In place of a sheath, two separate sheets can be used, 100 and 106, parts 102 and 104 being formed by another folded sheet in 103 and sealed in 101 and 105 to sheets 100, 106 respectively.

The width A of the opening of the pocket 120 when this pocket is "flat", naturally depends on the size of the lock chamber, on which the mouth is designed to be mounted.

More precisely, dimension A is nearly equal to the mount gap, close to, or slightly greater than the perimeter of the lock chamber.

Dimension B, which corresponds to the height of the pocket, is a function of the height of the lock chamber and of the dimensions of the gripping system and expansion to volume, located laterally. This area has the function of joining the bag to the lock chamber to prevent the development, on the flat surface of the bottom of the pocket, of constraints which could detach it from the lock chamber and thus break the confinement of the non-sterile area located between the exterior of the bag and the exterior of the lock chamber.

Beyond part B, the wall of the pocket 120 opens out in the direction of the bottom of the pocket 16, by a change in direction at an angle  $\alpha$  which is preferably greater than or equal to  $30^\circ$  and is situated at a distance C from the fold 103, short of it, which is equal to approximately  $A\sqrt{3}/6$ , or about 0.3 times the width of opening A of the flattened pocket.

This configuration means that when the pocket is expanded to volume, to give it a hexagonal shape the bottom of the pocket, initially folded as in line 103, will assume more or less a level and flat form.

Beyond the bottom 16, the seal lines converge strongly, then slightly along a length **D** then diverging along a length **E** and finally diverging more strongly towards the sides of the body 10 of the bag.

In this way a narrow area in the shape of a neck is obtained, through  
5 which the transfer will be carried out.

For information, dimensions **D** and **E** are approximately equal and correspond to the zone which will be threaded into the lock chamber after opening. They vary according to the construction of the lock chamber.

Dimension **F**, which corresponds to the narrowest passage of the neck,  
10 is 1.5 times smaller than the diameter of the passage of the lock chamber door.

In the bag which is the subject of the method of embodiment in figure 6, which carries the reference 1A, the transfer neck 11A is more or less perpendicular to the longitudinal axis of the bag, the pocket 120 opening laterally onto one of the sides of the bag.

Advantageously, this type of bag is constituted from a tubular sheath  
15 made of plastic material, in which the two lateral edges are flattened to form gussets **S**, one of the gussets passing by the mouth to make a gusset **S'** forming the pocket 120, with bottom 16.

Following peripheral sealing and cutting the shape of bag in figure 6 is  
20 obtained.

In this method of embodiment, will be noted on each side of the mouth 120, in the external parts 13, elongated openings 130. These are designed to facilitate the gripping of the mouth zone, either manually or by means of mechanical hooking, to facilitate the expansion to shape of the mouth and its  
25 adaptation on the lock chamber.

Bag 1B illustrated in figure 7 is formed from a folded sheath to form transversal (and not lateral) gussets **S** and **S'**.

One of these gussets **S'** corresponds to the pocket 120, on the sides of which will be noted the presence of openings 130 facilitating gripping, as has just  
30 been said in reference to figure 6.

It will be noted that bag 1B is equipped with a temporary airtightness or closure system 17, for example adhesive or with a slide, the function of which is to isolate at will the head of the bag from its contents. Thus, it is possible to transfer liquids or powders easily, but also to protect the contents from any contamination generated during the operations of connection or cutting.

It will also be noted that bag 1B is fitted with an appendage 18.

This is a tubular inflation appendage, which enables the pre-inflation of the bag. As soon as the pre-inflation is completed, the area which has been used for injecting the pre-inflation gas is reclosed by a seal line 180.

Bag 1C, shown empty in figure 8, is a large capacity bag. The body 10C of the bag has a generally rectangular or square shape and its corners, exterior to the main body, contain holes 131, designed to facilitate the handling and the stacking of the bags after they have been filled.

Figure 9 shows such a bag, with the reference 1'C, in which the neck 11C and the mouth 12 have been folded flat against one side of the bag.

Figure 10 shows the hexagonal shape of the pocket 120 when it is expanded to volume; the fold line 124', shown in broken lines, is no longer visible - or nearly no longer visible - due to the tensioning of the bottom of the bag, which takes the form of a level or more or less level partition.

As will be seen below, it is this partition which will be cut to enable the transfer of the products or articles contained in the bags into the sterile enclosure.

In the event that the interior of the bag is under vacuum, or at low pressure, the pre-inflation mentioned above is required to enable flattening of the partition which constitutes the bottom of the bag.

The lock chamber shown in figure 11 essentially comprises an exterior part 2, fixed, and an interior, mobile, part - or door - 4.

Part 2 has the overall form of a generally tubular sleeve, with an axis kk', composed of a circular base 20 and a hexagonal head 21.

The base 20 is designed to be fixed by appropriate means, in an airtight fashion, onto the entry opening of a sterile enclosure.

In figures 14 and 16, the reference 201 has been given to the wall of the enclosure and the reference 200 to its interior, sterile space; with the aim of simplification, the base 2 has been shown as forming an integral part of the wall 201.

5 In figure 11, 210 has been used to designate the lateral sides of the hexagonal part 21, and reference 211 its frontal, flat side, which is perpendicular to the axis  $kk'$  of the sleeve 2.

The mobile lock chamber element 4 has the general form of a disc, which can move axially in the interior of the fixed part 21, to retract into the enclosure 200 when the lock chamber is open.

10 In contrast, when the lock chamber is closed, its frontal face 40 is found more or less in the same plane as face 211.

A discoid telescopic piston 6 can also slide within the interior of part 4, coaxial to part 4.

15 In a retracted position in the interior of part 4, the frontal face 600 of the piston 6 is located in the same plane as the above-mentioned face 40 (see figures 14, 15 and 18). In contrast, in another position (see figures 12 and 13) the face 600 of the piston projects in relation to the face 40.

The piston 6 is pierced by an axial bore 60 which opens into a bore coaxial to the part 4 and is connected to a pipe 42 in which the end 43 is connected to a vacuum outlet, via an appropriate control valve.

20 This pipe 42 also communicates, via channels 41, of which only one is shown in figures 12 and 13, with the frontal ring surface 40 of the part 4, located to the exterior of the piston 6.

25 In a similar fashion, channels 22 drilled in the fixed part 20 of the lock chamber, of which only one is illustrated in the drawings, open onto the frontal surface 211 of the fixed part 2; their end 23 is connected to a vacuum outlet, via a control valve.

30 Parts 2 and 4 are each equipped with a heatable cutting blade with closed outline, this outline being in circular form in the method of embodiment illustrated.

As will be seen in more detail in figure 13, these blades have bevelled cutting edges and come into mutual contact at their tip. The angle  $\alpha$  is of the order of 20 to 30°.

The exterior blade, integral to part 2, carries the reference 3; the  
5 interior blade, integral to part 4, carries the reference 5.

The interior opening of part 2 has a slightly flattened cone shape, with its top angle pointing towards the exterior of the enclosure. The lateral wall of part 4 also has a flattened cone shape, but arranged inversely (top angle pointing towards the interior of the enclosure 200).

10 The blades 3 and 5 are located in the extension of the above-mentioned walls and are applied against each other lightly by force, which implies their elastic deformation, of low magnitude; this "tight" diametral contact ensures airtightness at the line of closed contact between the two blades.

For information, the angle  $\beta$  (see figure 13) formed by the dorsal faces  
15 of blades 3, 5 is of the order of 20°.

The set of blades 3, 5 projects slightly in relation to surfaces 211, 40 mentioned above, when the door occupies its closed position illustrated in figures 12 and 13.

In the method of embodiment illustrated in figures 12 to 21, the axis of  
20 the entry opening of the enclosure and correlatively the axis  $kk'$  are vertical, the blades 3, 5 being turned upwards.

Appropriate means of fixation enable the maintenance of the door 4 in its closed position.

In the example illustrated, these means are of the type using rapid  
25 connection by partial turn, comprising peripheral lugs integral to part 4, capable of engaging and locking into a groove 25 fitted into the interior wall of part 2.

Appropriate means, not shown, are provided which enable the door 4 to be unlocked and to be retracted into the interior of the enclosure, as is illustrated diagrammatically in figure 16.

30 This implies, of course, that the pipe 42 is flexible.

On the assumption that the interior of the sterile enclosure is accessible to the gloved hand of an operator, the manoeuvring of the door can be done manually. The blades 3 and 5 are metal, and are designed to be heated by induction, by means of one or several coils 24 through which a high frequency  
5 alternating current is run.

Depending on the dimensions of the aperture of the lock chamber passage or on other parameters affecting the efficiency of the heating of the blades, the high frequency induction coil(s) can be placed either in the fixed part 2 or in the mobile part 4.

10 In the example illustrated, the coils 24 are housed in part 2.

The constituent materials of parts 2 and 4 are of course amagnetic insulating materials, resistant to high temperatures.

This means, for example, a composite material based on cotton and bakelite; preferably between the blades and their holder a layer of PTFE  
15 (polytetrafluorethylene) is allowed for.

The heating system is preferably selected so as to ensure a heating temperature of the blades to 200°C.

On the exterior of the fixed head 21 there is an inflatable ring collar 7

The dimensions of the bags and the lock chamber will of course be  
20 selected according to the products or articles which are to be contained in the bags then transferred into the sterile enclosure.

For information, a bag could have an overall length of 800 mm and a width of 400 mm, while the diameter of the door 4 of the lock chamber would be of the order of 80 mm.

25 By referring to figures 12 to 18 we are now going to describe in what manner the transfer is carried out of products or articles contained in a bag 1, previously sterilised, into the interior of a sterile enclosure 200.

Initially, the door 4 of the lock chamber is closed, the closure systems 43, 25 being in door-locked position, the position illustrated in figure 12.

30 In standard form, there is a slight overpressure in the interior of the sterile enclosure 200, for example of the order of 60 Pascal, in relation to



atmospheric pressure, which prevents the unexpected entry of outside air, liable to contain particles or micro-organisms, notably through the contact zone between the two blades 3 and 5.

5 The bag has been mounted from top to bottom onto the hexagonal part 21 of the lock chamber, inside the sleeve 7 after which this is inflated, in order to ensure the retention of the pocket on the lock chamber.

Air under pressure is also introduced into the pipe 42, so as to make the piston 6 move up into the position illustrated in figures 12 and 13, which has the effect of tensioning the partition 16 ensuring that this is distanced from the set  
10 of blades 3 and 5.

As already said, if necessary, a pre-inflation of the bag by sterile atmosphere is carried out to enable the separation of the bottom of the pocket from the surfaces which were stuck to this bottom (adjacent surfaces).

The electrical supply to the coils 24 is then switched on, which has the  
15 effect of heating the two blades 3 and 5 by induction.

These are taken up to the required temperature, for example of the order of 200°C, for a few minutes, enough to sterilise the blades; then the temperature is allowed to drop towards 120°C, to cut the plastic material of the partition 16 by fusion, the pipe 42 is connected to a vacuum pump by the opening  
20 of an appropriate valve, not shown.

In the same way, the channels 22 are connected to a vacuum outlet.

For information, the pressure (negative) of this placing under vacuum is of the order of  $2 \cdot 10^{-4}$  Pascal.

In this way the piston 6 is caused to move downwards and its  
25 retraction in the door 4 is also initiated, while sucking the partition 16 downwards and applying it against the set of circular blades 3, 5.

As a result of this operation, the non-sterile air found outside the lock chamber and outside the bag, on the one hand in the interior space E1 in relation to the door 4 and on the other hand in the exterior space EE, is eliminated.

The vacuum combined with the fusion of the plastic will cut the partition and, on each side of the blades, will create an airtight contact between each cut part of the partition 16 and the corresponding part of the lock chamber.

These airtight contacts enclose the non-sterile areas.

5 As illustrated in figures 14 and 15, as a result of the fusion of the plastic material, the contact of the material with the blades is effected using strips which provide a total or virtually total airtightness at that point.

In figure 15, references 160 and 161 have been used to designate the circular strips which border the cut interior part 16i and the cut exterior part 16e, respectively, of the bottom of the pocket.

10 In practice, the cut parts of the partition, 16i and 16e, have just been applied against the fixed surfaces 600 and 40 on the one hand and 211 on the other; however, in order to improve the clarity of the drawings, a slight gap has been preserved in the figures in these areas.

15 By comparing figures 13 and 15, it will be understood that only the exterior cutting parts of the blades (located between the strips 160 and 161) are now located inside the bag, that is in a sterile zone, though they were initially exposed to a non-sterile atmosphere.

20 However, as a result of the heat sterilisation of the blades at a high temperature, and due to the fact that the cutting parts of the blades have been subject to wiping by the plastic material in fusion during cutting, any bacteria or micro-organisms which might have been found on these surfaces have been eliminated.

25 Of course, this guarantee of sterility cannot be met if, after cutting, the plastic remains in contact with the cutting blade, the blade must therefore be composed of a sharp zone for cutting and of a holding zone for after cutting, which is the case with the configuration of blades illustrated in the drawings.

30 Naturally, the vacuum continues to be applied in the pipe 42 and in the channel 22, so as to press the strips 160, 161 against the corresponding blades 5 and 3.

Following cooling of the set of blades 3, 5, one proceeds to the opening of the lock chamber. To do this, the door is unlocked, by disengaging parts 43 and 25 and the mobile part 4 inside the sterile enclosure 200 is brought down, as illustrated in figure 16.

5 To improve the legibility of this figure, one part of the wall of the enclosure has been artificially turned back at a right angle, with the reference 201', into which the pipe 42 is fitted.

The discoid part of the partition 16i remains stuck through suction against the retracted door, which has the reference 4', inside the sterile enclosure.

10 This is not a problem, insofar as it is the sterile surface of part 16i - a surface which was inside the bag before cutting - which is exposed to the sterile environment of the enclosure. In contrast, the contaminated air located on the other side of the plastic disc 16i is confined in the space EI, in an airtight manner, as a result of the presence of the ring strip 160 and the maintenance of the vacuum  
15 in part 4.

In view of the transfer of products from the bag 1 into the sterile enclosure 200, the neck of the bag 11 is threaded and turned over (in the same way as a sock) in the opening of the lock chamber, as is illustrated in figures 16 and 17. This has the effect of protecting the bag's contents from contact with the  
20 exterior blade 3 and preventing damage to or contamination of the contents by the blade.

It will be noted that only the sterile surface of the neck 11 (the side which was located inside the bag) will partially enter the interior of the enclosure 200.

25 The transfer of the products from the inside of the bag into the enclosure can then be effected, as is symbolised by the arrow G in figure 16.

Once the operation is completed, the door is reclosed, to return to the position illustrated in figure 12, then locked.

The vacuum sources are then disconnected from the pipe 42 and the  
30 channels 22, by activating the valves provided, and the clamping sleeve 7 is deflated.

The empty bag 1 is then removed and - in the same way - the exterior cut part 16e (which is attached to it), after which the plastic disc 16i is removed.

The lock chamber is now ready for a new, similar operation on a new bag.

5 Naturally, following cutting and before transfer, the door is only opened once the blades have been correctly cooled.

To limit the waiting time, it is advantageous to provide a cooling system for the blades, for example by circulating a cooling fluid in the interior of parts 2 and/or 4.

10 In the method of embodiment of the system illustrated in figures 19 to 21, a lock chamber has to be dealt with which is mounted in a removable fashion on the wall 201 of the sterile enclosure 200.

The wall of the enclosure and the base 20 of the part 2 of the lock chamber have supplementary means of fixing 202, 203, for example using a bayonet or a partial turn.

The situation illustrated in figure 19 corresponds to an incomplete emptying of the bag 1, in which only some of the products have been transferred into the enclosure 200, by implementing the method described above.

20 At this point, a cessation of distribution is required and the products which have not been transferred must be maintained in the interior of the bag in a sterile atmosphere

To do this, the door 4 has been reclosed, and heat-cutting is carried out, with sealing of the two edges of the cut, in the median part of the transfer zone 11.

25 The line of cut 112 separates two partitions 113, 114, the first integral to the mouth zone 111 and the second integral to the part 110, attached to the bag 1.

During this cutting - sealing operation, the sterility of the interior of the bag has not been tainted.

The enclosure is fitted with a double door 26, 27 which is reclosed, the door 26 closing the entrance of the enclosure, while the door 27 closes the exit from the lock chamber.

5 The lock chamber is removed with the mouth of the cut bag, which carries reference 111' (cf. figure 20).

The remaining part of the bag 1 is then adapted to an airtight door collar 8, this adaptation being achieved using the part of the neck 110 previously turned over.

10 The door collar 8 possesses a peripheral locking groove 204 similar to the groove 203 on the lock chamber so that it can be adapted to the locking elements 202 of the enclosure and be fixed in an airtight manner to it.

The collar 8 is closed in an airtight manner by a door 83.

15 The turned back neck 110 having been fixed to a ring piece 80 integral to the collar 8, a new pocket with bottom 114 is obtained, in which the interior space 120' is not sterile.

In a known manner, the door collar 8 contains entry 81 and exit 82 openings which are equipped with filters or valves isolating them from the exterior and which enable the circulation - symbolised by the arrows H - of a gas or vapour capable of sterilising the interior of the pocket 120'.

20 When sterilisation is complete, the bag is equipped with the double door transfer system and will thus be able to be re-used.

To do this, the collar 8 and the bag 1 are fitted onto the entrance to the enclosure 200 and the doors 26, 83 are opened after which the partition 114 is broken to enable penetration into the interior of the opening of the enclosure to  
25 form a funnel 114'.

The rest of the products contained in the bag can then be transferred into the sterile enclosure, as symbolised by the arrow G

The layout illustrated in figure 22 has the aim of protecting the interior of the bag's transfer pocket from contamination during transport.

30 In this figure, the same references as in figure 4 have been used to designate the various folds in the plastic sheet at the mouth.

The walls 100 and 102 on the one hand, and 104 and 106 on the other are joined to each other by seal lines 107, 108 respectively.

At the edge of the pocket these two assemblies are also joined by a seal line 109.

5           These various seals keep the different surfaces of the walls away from the exterior air.

The protective seal 109 will be cut just before the connection of the pocket to the lock chamber in readiness for the transfer.

10           Naturally, it would be possible to allow for other methods of protection, notably by using an adhesive strip which closes the pocket or by an overwrapping bag.

15           The method of embodiment of the bag illustrated in figure 23 is intended to receive a roll R of material in sheet form. As the roll is emptied, the transfer of the sheet, symbolised by the arrow J, into the sterile enclosure is carried out in a similar fashion to that pertaining to individual articles or loose products.

It will be noted that the bag contains an additional, lateral pocket into which it is possible to introduce and withdraw mechanical equipment Z for emptying the roller, as symbolised by the double arrow I.

20           The roller R could also, of course, carry materials in thread or tube form.

25           In the variant illustrated in figure 24, the external face of the pocket 120 is equipped with a series of fittings to enable gripping 132. These are small bands of plastic material which are sealed around the mouth in such a way as to make small hoops, at four of the corners of the hexagon obtained when the pocket is expanded to shape.

Means of expanding the pocket to shape can be provided which have hook fittings which act with the bands 132 and possibly with the elongated holes 130, to give volume to the pocket and fit it onto the lock chamber.

30           In the variant illustrated in figure 25, the same references have been used to designate the different folds in the sheet around the mouth as in figure 2.

It should be noted that the two parts 121, 123 on the one hand and 125, 127 on the other are both folded towards the exterior at 180°, forming folds 128.

5 The raised exterior folds, designated 128', thus form a peripheral groove 129 which is capable of receiving, by interlocking, an element for the expansion to shape and rigidification of the pocket; this element is designated by the reference 9 and is shown in figure 26.

The element 9 is of a rigid material, for example metal or plastic material.

10 It has the general shape of a hexagonal sleeve, composed of two half-shells 9a, 9b, separated by longitudinal slits 90 but joined by a pair of ears 91 placed at the top end of the slits.

Each half-shell 9a, 9b, carries on its upper part a handle 92 which extends outwards, in an oblique direction and jutting out at an angle of 90° in  
15 relation to the ears 91.

The element 9 is shaped in such a way that it is possible, by manipulating it with the handles 92, to pass it onto the mouth of the bag. then (by moving in the opposite direction) to introduce it into the interior of the peripheral groove 129 mentioned above, which ensures the expansion to shape and the  
20 rigidification of the pocket 120.

The presence of the slits 90 and the ears 91 is designed to enable the passage of the elements 9 onto the free edges 13 of the mouth of the bag when the element is put in position.

In the preceding description, the bag used is entirely composed of  
25 flexible plastic material, which is relevant in terms of the manufacturing cost of the bag and its compactness when empty.

It goes without saying that it would not be departing from the framework of the invention to allow for a container-type bag composed of a rigid body with a pocket-shaped mouth; it is only important that the bottom of the  
30 pocket should constitute a flexible partition capable of being heat-cut by the blades.

The exterior wall of the lock chamber could be of a different shape from a hexagonal one, notably a square, rectangular or circular shape.

5 The hexagonal shape is useful for a flexible pocket, initially flat, as it enables the proper levelling of the partition at the bottom of the pocket at expansion to volume; in addition, this shape is similar to the circular shape of the blades and enables a good level of airtightness between the bag and the lock chamber.

10 Instead of heating the cutting blades by induction, heating elements with low thermic inertia could be used; this solution is applicable in particular for lock chambers with large diameters.

15 The retention of the pocket on the fixed part of the lock chamber could be effected by using an interior inflatable seal (and not exterior as in the method of embodiment described above). In this case, the inflatable seal is placed around part 21 and presses the lateral wall of the pocket towards the exterior, against a fixed ring piece.

20 The system which is the subject of the invention is not limited to the transfer of sterile products, it is also suitable for the transfer of products or components in which the isolation and confinement in relation to the exterior air must be guaranteed; such as is the case for toxic, harmful, pathogenic, radioactive or air-sensitive products in particular.

25 The system is particularly suited for use in the pharmaceutical or cosmetics industry, for the transfer of radio-sterilised plastic packaging bottles or components into a sterile enclosure where they will be filled, stoppered, closed, sealed, etc. in a sterile manner.



CLAIMS

1. Transfer system between a bag (1) and a sterile enclosure (200),  
5 characterised in that:

a) the bag (1) presents at least one mouth (120) in the form of a pocket, of which the bottom is constituted by a flexible partition (16) which separates the interior spaces of the pocket and the bag (1), and is able to be heat-cut;

10 b) the entrance of the enclosure (200) is equipped with a lock chamber composed of an exterior, fixed part (2) in the form of a sleeve, and an interior, mobile part (4) constituting the door of the lock chamber;

c) the fixed (2) and mobile (4) parts are each provided with a heatable blade with closed outline, one exterior (3), integral to the fixed part, and  
15 the other interior (5), integral to the mobile part, these two blades (3, 5) overlapping and being joined at their apex in an airtight manner when the lock chamber is in the closed state;

d) the lock chamber (2, 4) and the mouth of the bag (120) in the form of a pocket are shaped in such a way that it is possible to mount this mouth  
20 (120) onto the exterior part (2), the flexible partition (16) then becoming positioned in relation to the set of blades (3, 5) (lock chamber closed);

e) the lock chamber is equipped with vacuum outlets capable of applying the flexible partition (16) by means of suction against the heatable blades (3, 5) and effecting its cutting by fusion of the areas which come into contact with  
25 the blades.

2. Transfer system according to claim 1, characterised in that the said fixed part (2) of the lock chamber has a polygonal-shaped head (21), hexagonal for example, on which the mouth of the bag (120) is mounted.

30

3. Transfer system according to claim 1 or 2, characterised in that it includes means of holding the mouth of the bag (120) on the fixed part (2), for example an inflatable sleeve (7).

5                   4. Transfer system according to any one of claims 1 to 3, characterised in that vacuum outlets (41, 22) are provided both in the interior and on the exterior of the set of blades (3, 5), close to them.

10                   5. Transfer system according to any one of claims 1 to 4, characterised in that the said blades (3, 5) are metal blades heated electrically, for example by a high frequency current or by Joule effect.

15                   6. Transfer system according to any one of claims 1 to 5, characterised in that the lock chamber is provided with means (24) of cooling the blades.

7. System according to any one of claims 1 to 6, characterised in that the blades (3, 5) have a circular outline.

20                   8. System according to any one of claims 1 to 7, characterised in that the mobile part (4) of the lock chamber is provided with a central sliding element (6) forming a piston, traversed by a vacuum channel (60) and in which the frontal face (600) is adapted to serve as support for the central zone of the partition (16).

25

9. System according to any one of claims 1 to 8, characterised in that the said lock chamber is fitted at the entrance to the enclosure in such a way that it can be removed, as an airtight door collar (8) can be fitted in its place.

10. Bag for transfer system according to any one of the preceding claims, characterised in that it is of plastic material and is made by heat-sealing from a plastic sheath or sheets and presenting, flat, a transfer zone (11) presenting a mouth constituted by a folded zone, capable of being expanded to shape to form  
5 a pocket (120) with a level bottom (16) adaptable to the lock chamber (2, 4).

11. Bag according to claim 10, characterised in that the transfer zone is created by a seal in the folded zone comprising a change in direction at an angle (a) greater than or equal to  $30^\circ$  and located at a distance (C) from the fold  
10 (103), and short of it, which is equal to approximately 0.3 times the opening width (A) of the flattened pocket

12. Bag according to claim 10 or 11, characterised in that the neck above the transfer zone (11) is shaped in such a way that it can be turned over and  
15 threaded onto the fixed part of the lock chamber (2) following opening of the lock chamber, to make a funnel and to protect the contents of the bag from contact with the exterior blade (3).

13. Bag according to any one of claims 10 to 12, characterised in  
20 that it is shaped in such a way that it is possible to make it temporarily airtight (112) which isolates the interior of the bag from the transfer zone (111).

14. Bag according to any one of claims 10 to 13, characterised in that the internal surfaces of the mouth (120) in pocket form are protected from  
25 contamination by at least one airtight seal (109, 107-108)

15. Bag according to any one of claims 10 to 14, characterised in that it includes at least one inflation appendage (18).

16. Bag according to any one of claims 10 to 15, characterised in that it is provided, at its mouth, with means of gripping (130, 132), facilitating the expansion to shape of the pocket and its mounting on the lock chamber (2-4).

5 17. Bag according to any one of claims 10 to 16, characterised in that its mouth (12) is folded double, in such a way as to form a peripheral groove (129) capable of receiving, by means of interlocking, an element (9) for the expansion to shape and rigidification of the pocket (120).

FIG.1

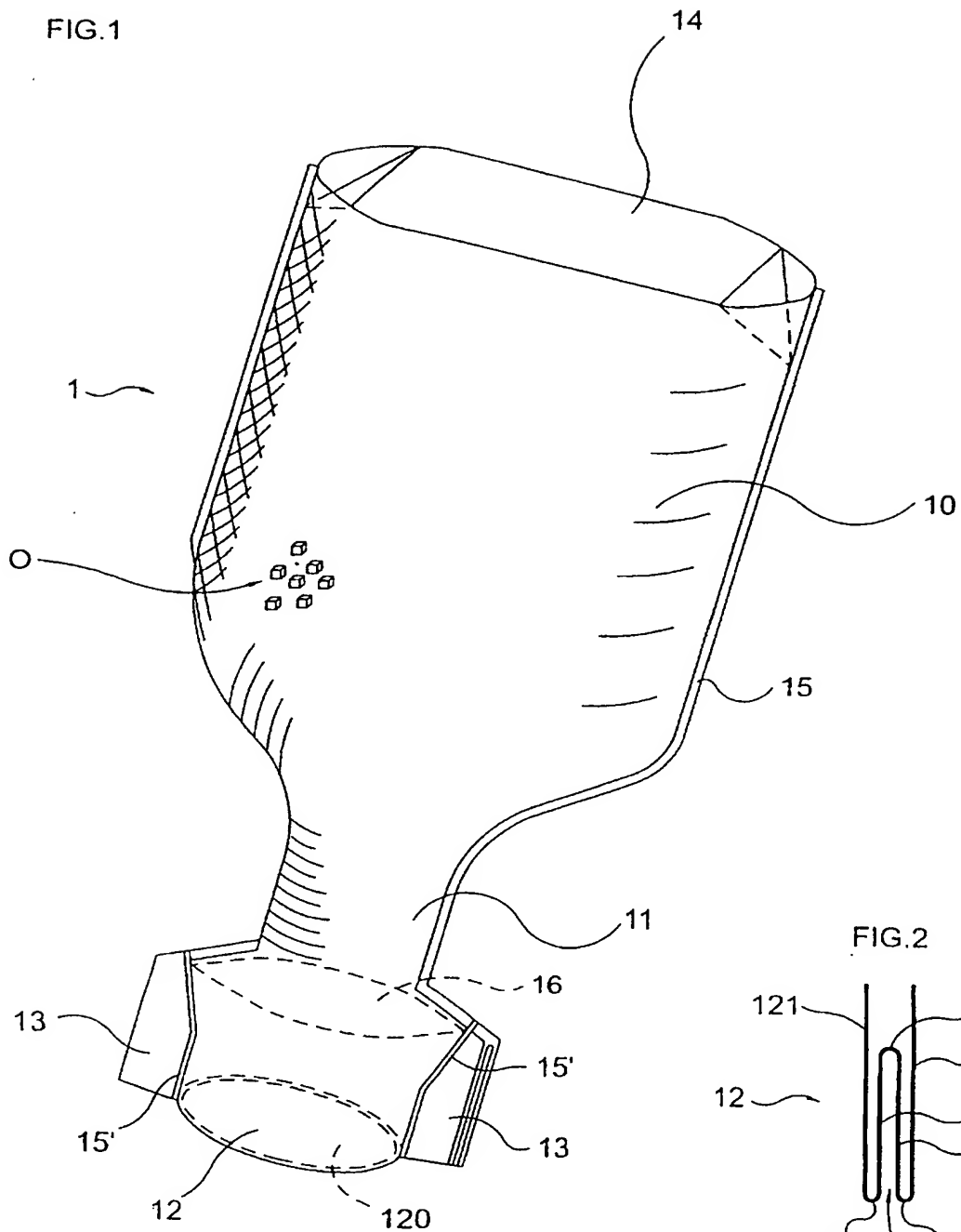
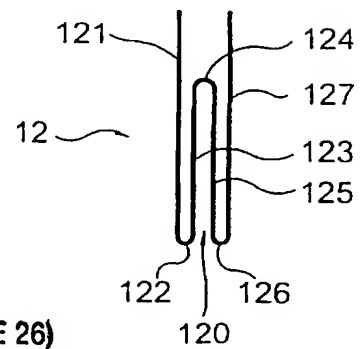


FIG.2



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2/12

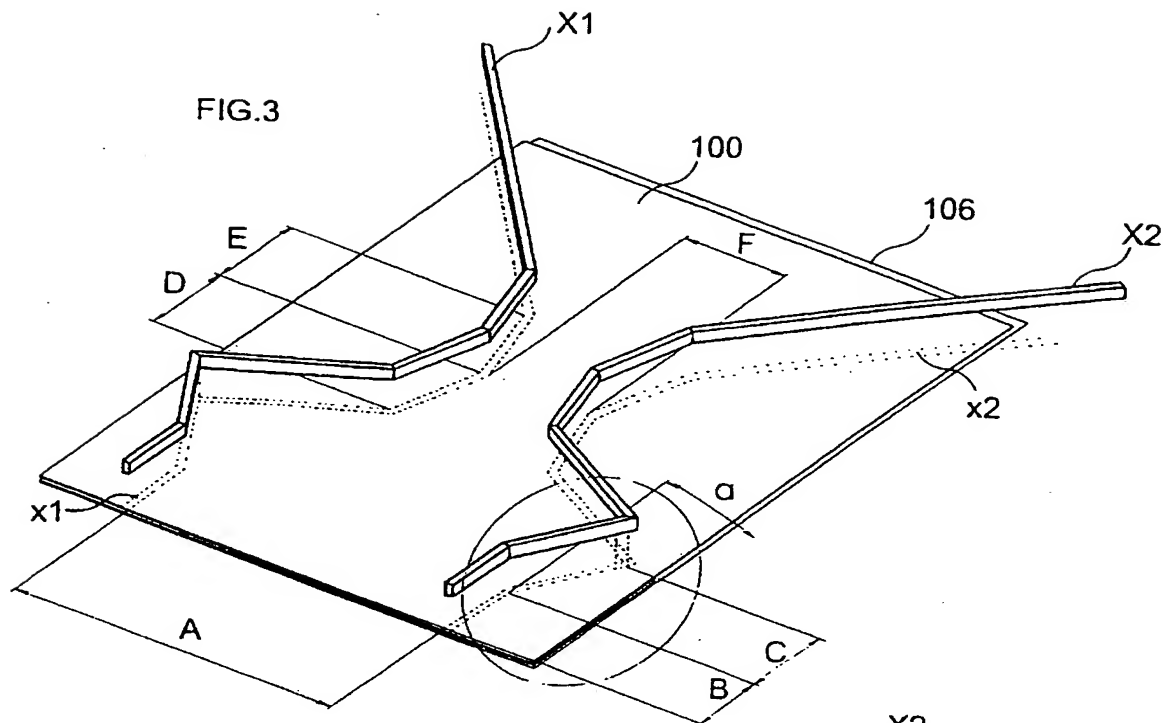


FIG.4

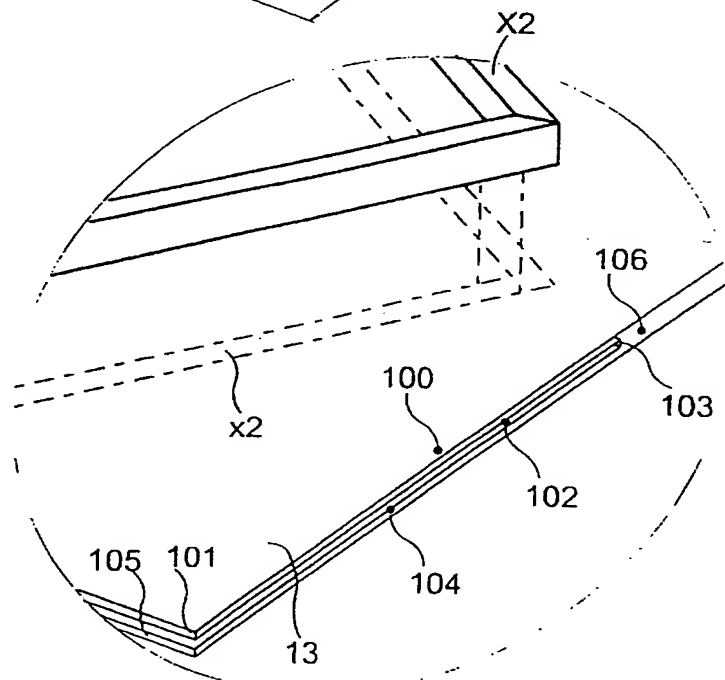
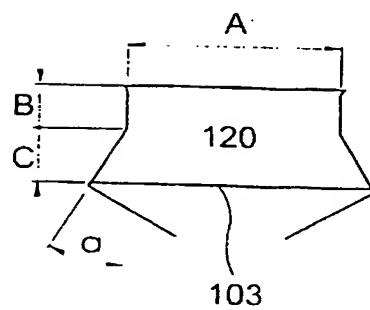


FIG.5



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FIG.6

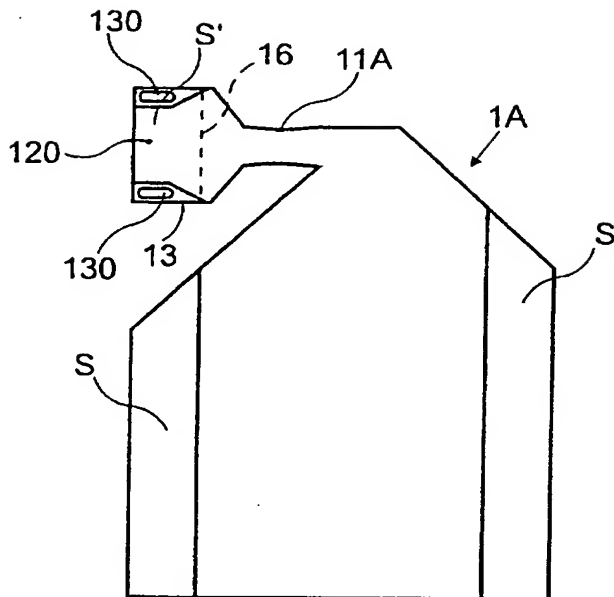


FIG.7

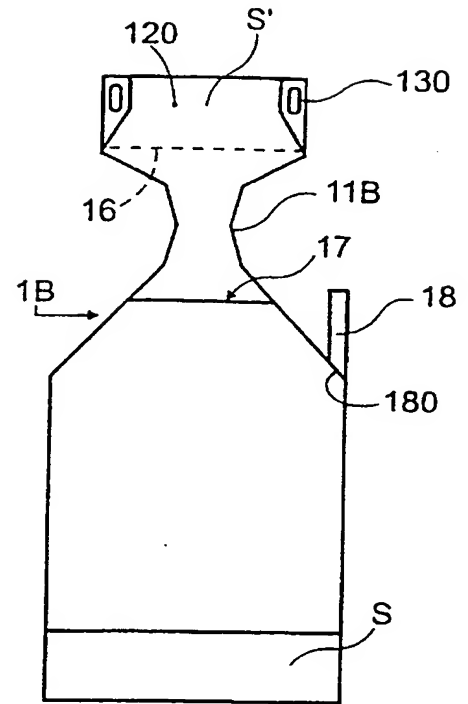


FIG.8

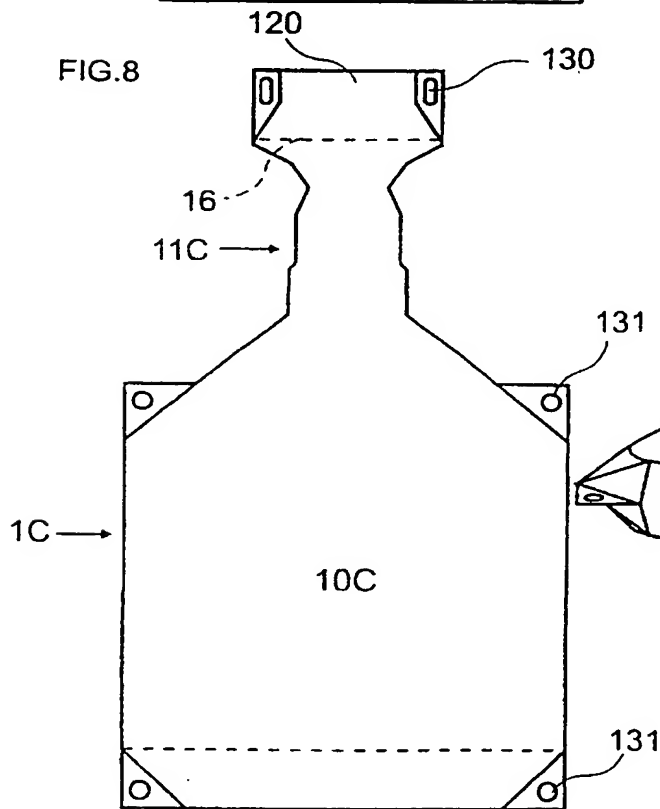
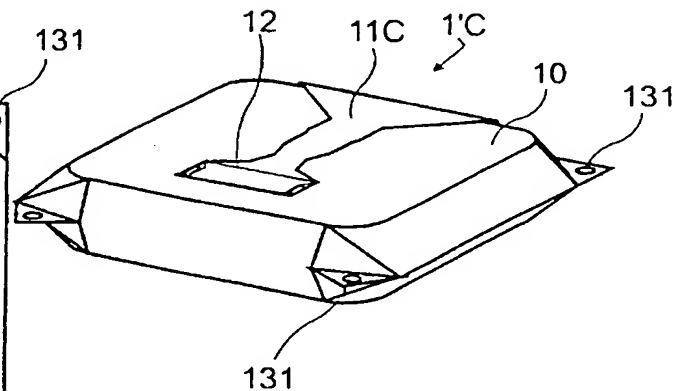


FIG.9



4/12

FIG.10

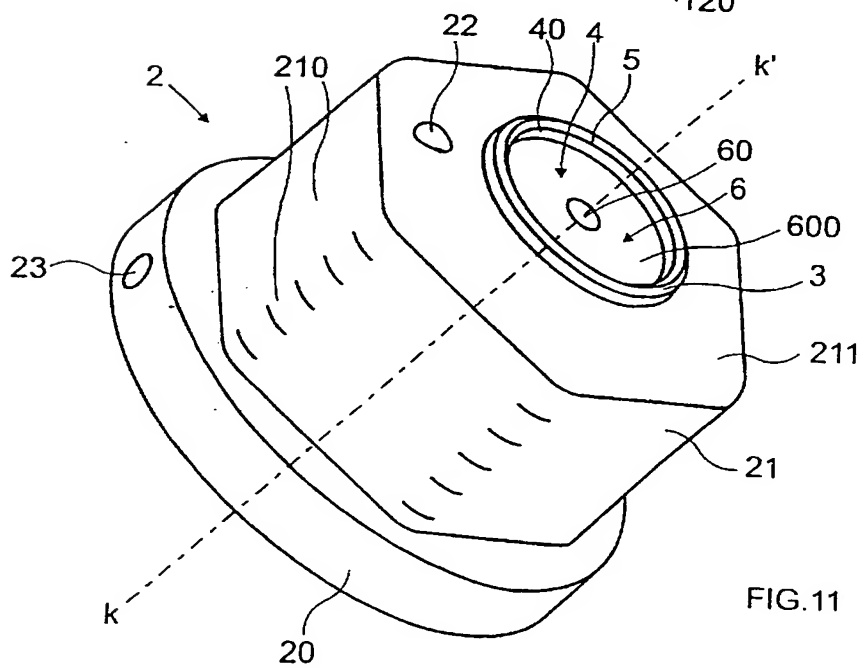
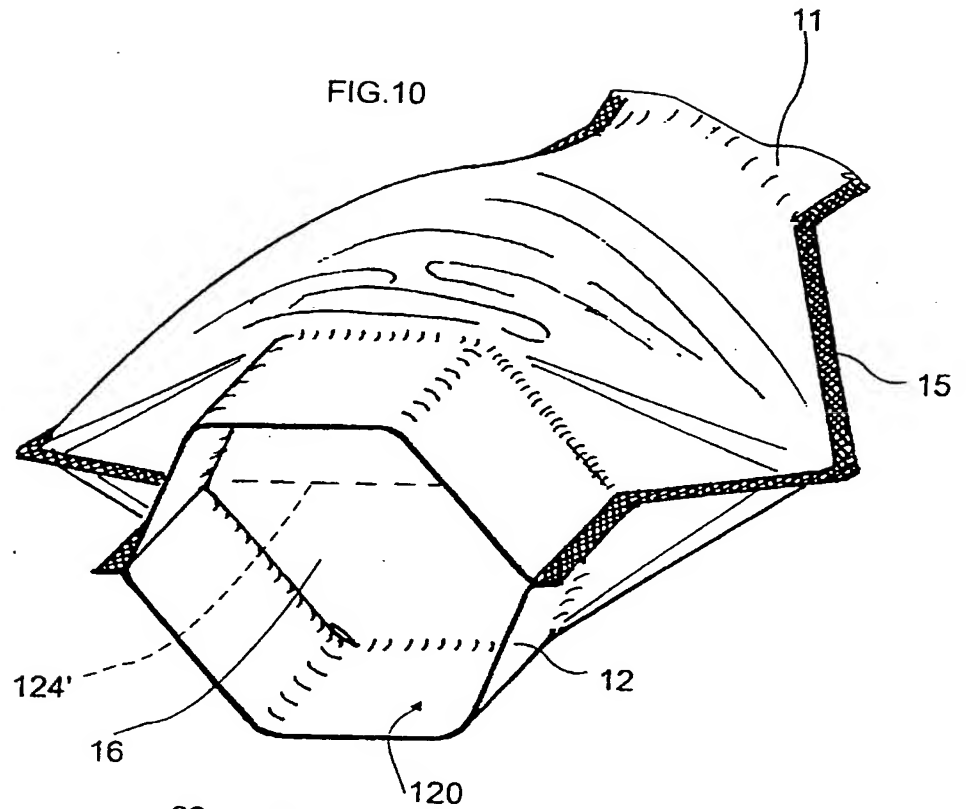


FIG.11



FIG. 12

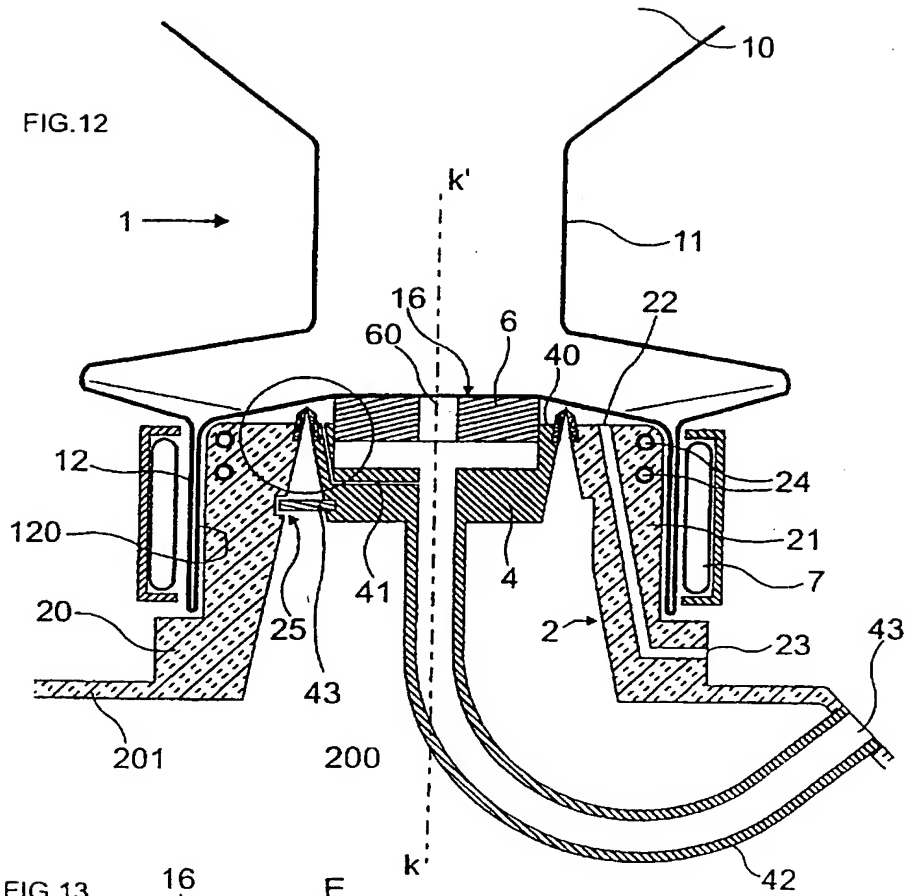
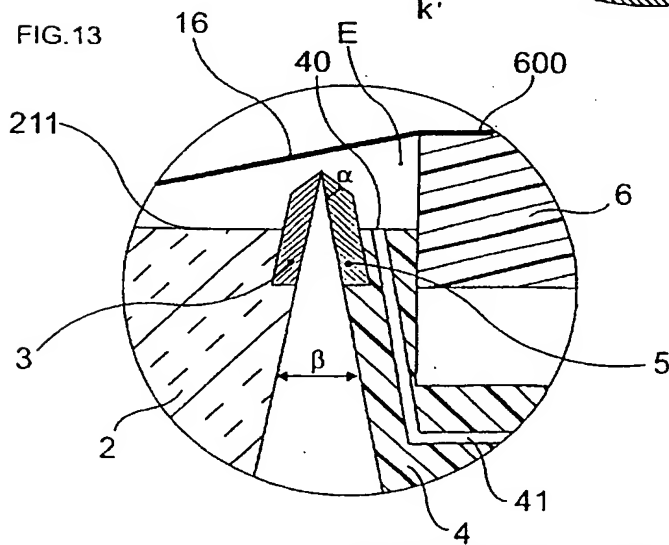


FIG. 13



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6/12

FIG.14

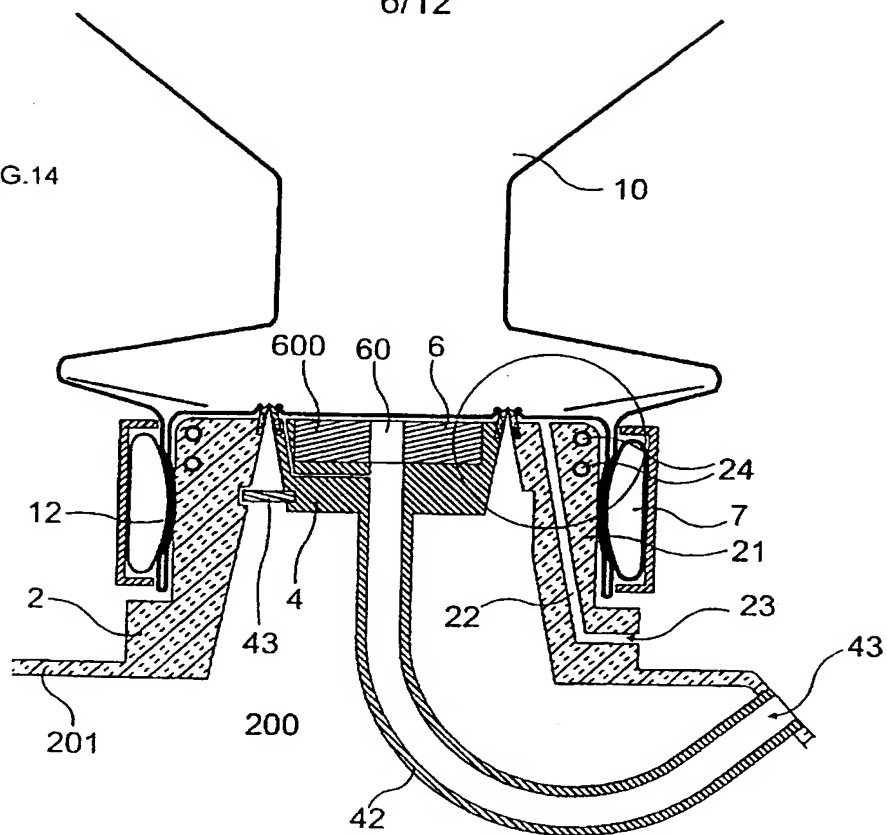


FIG.15

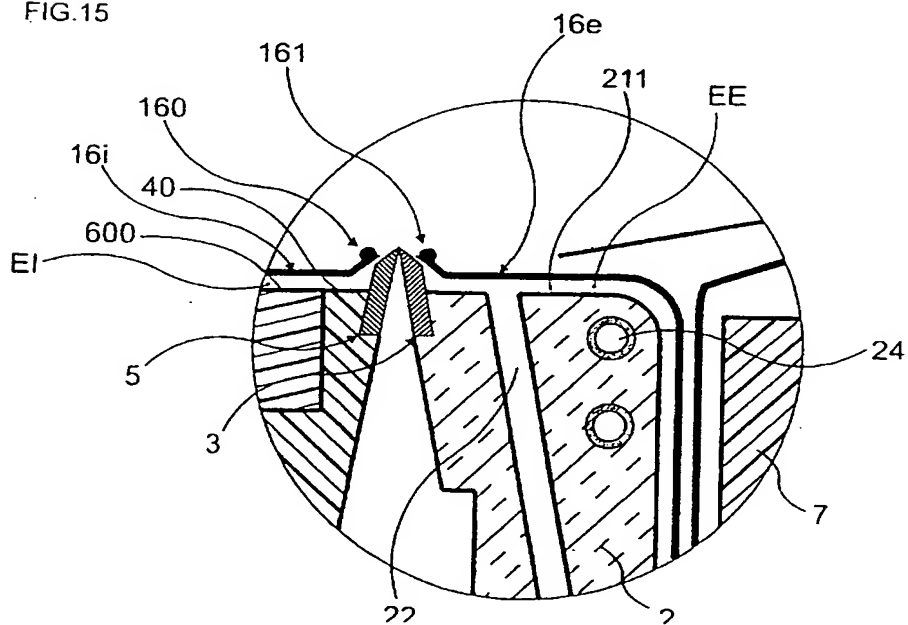


FIG. 16

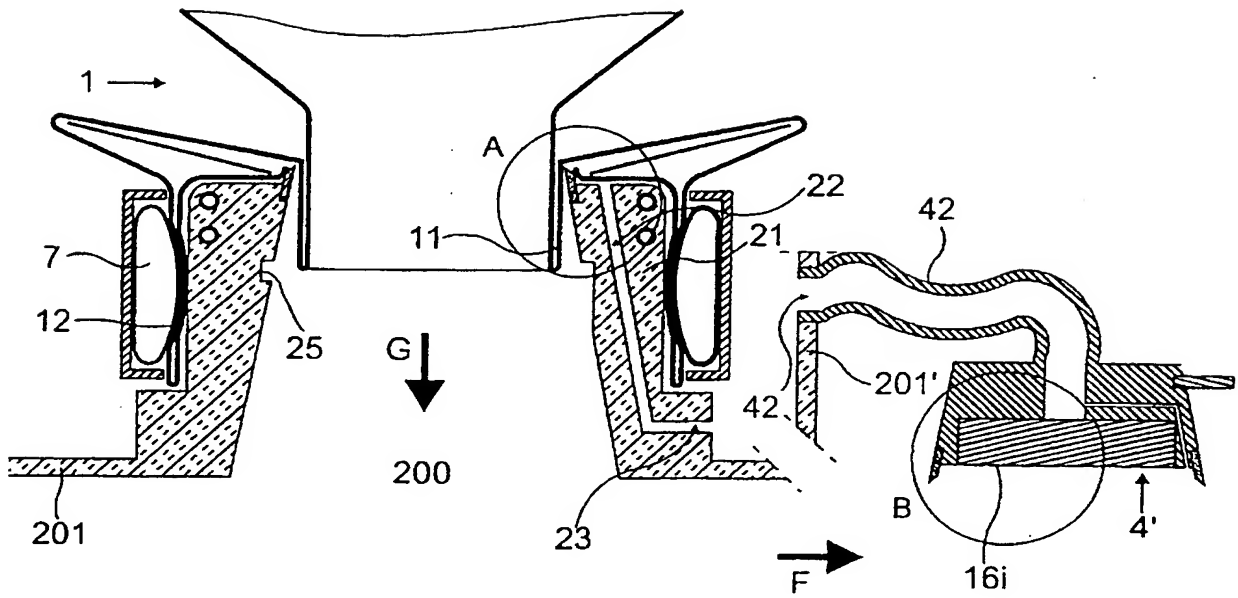


FIG. 17

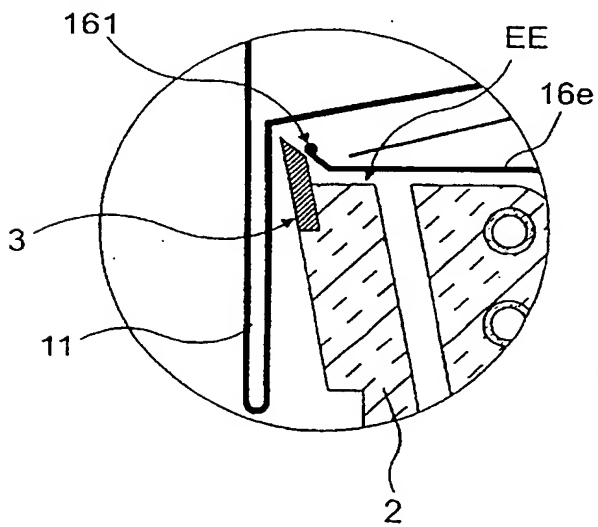
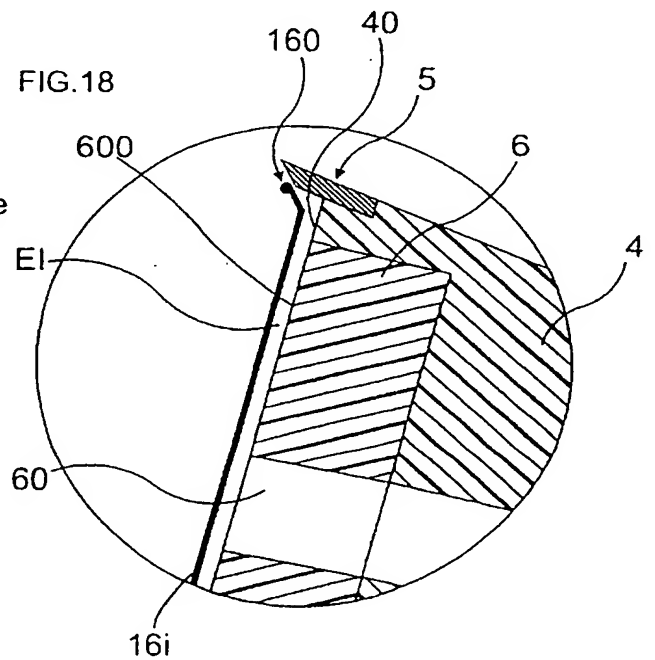


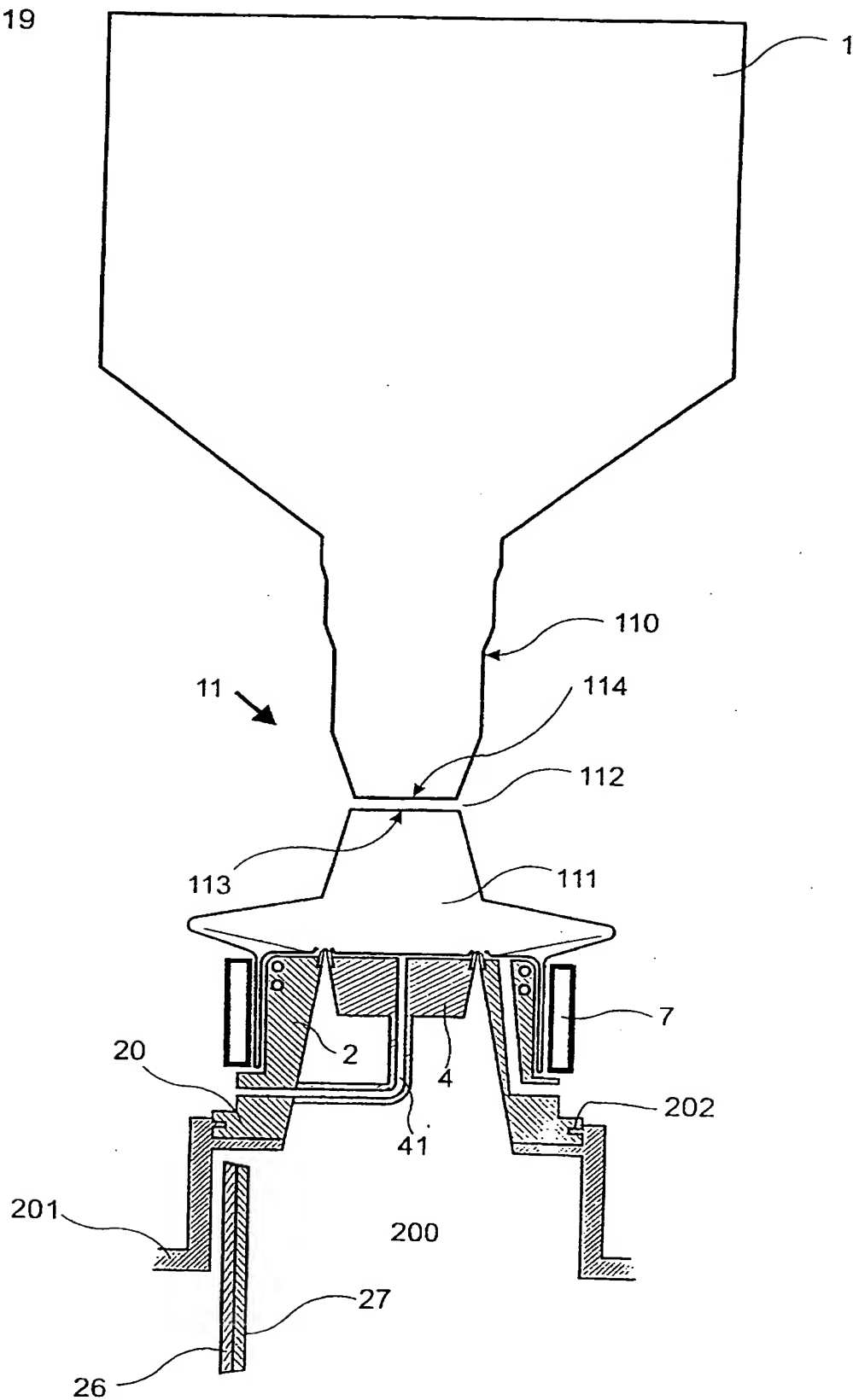
FIG. 18



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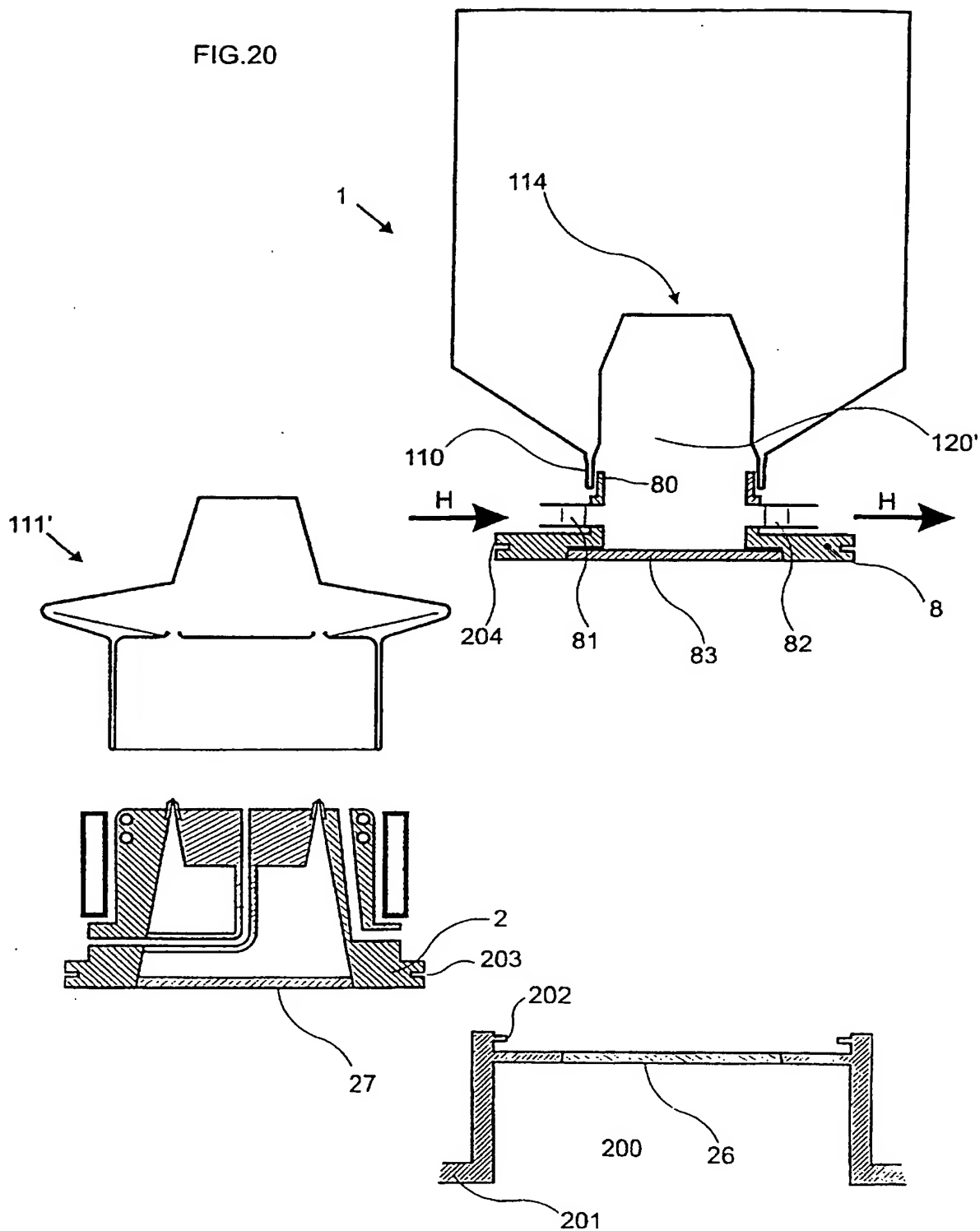
8/12

FIG.19



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FIG.20



10/12

FIG.21

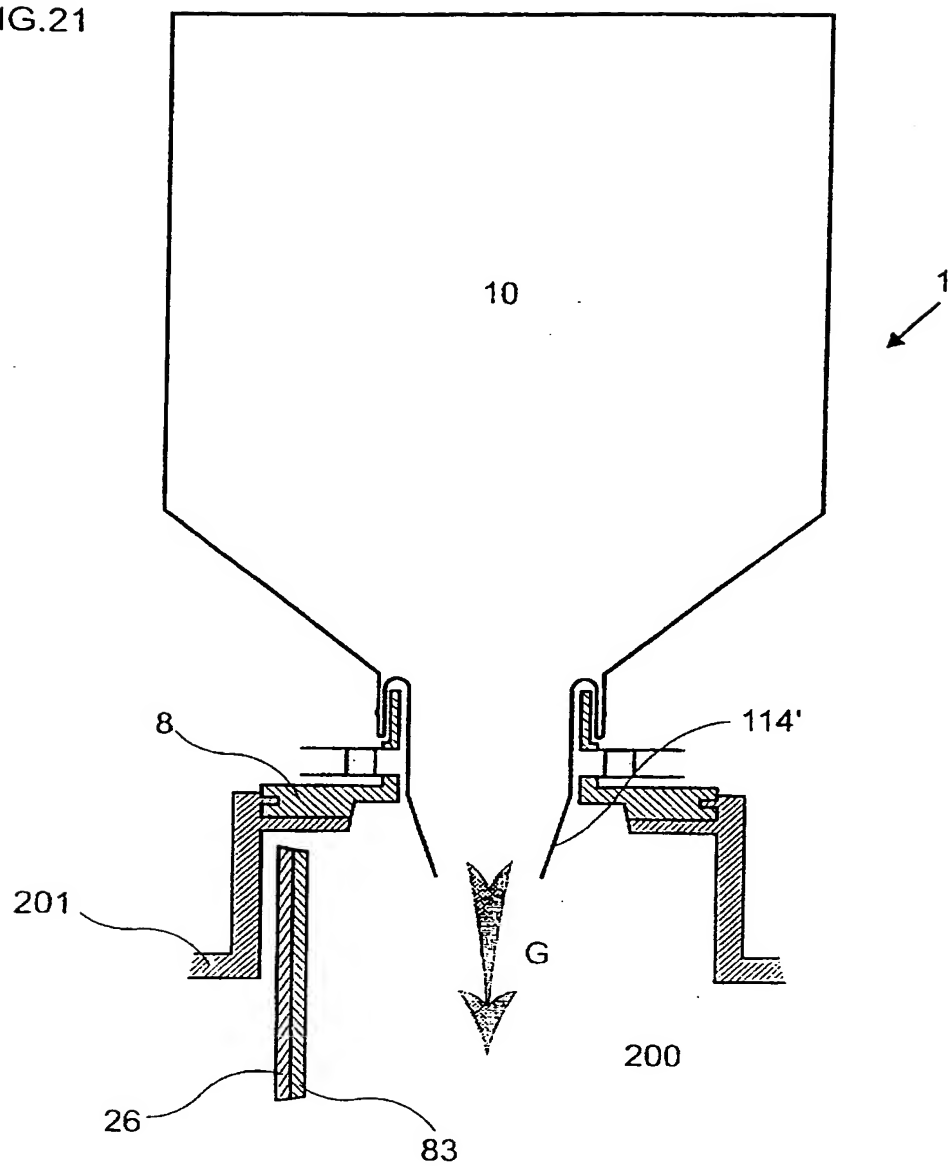
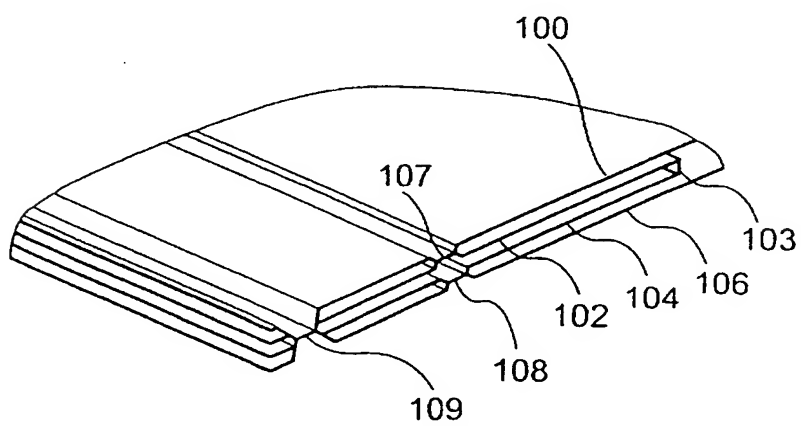


FIG.22



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FIG.23

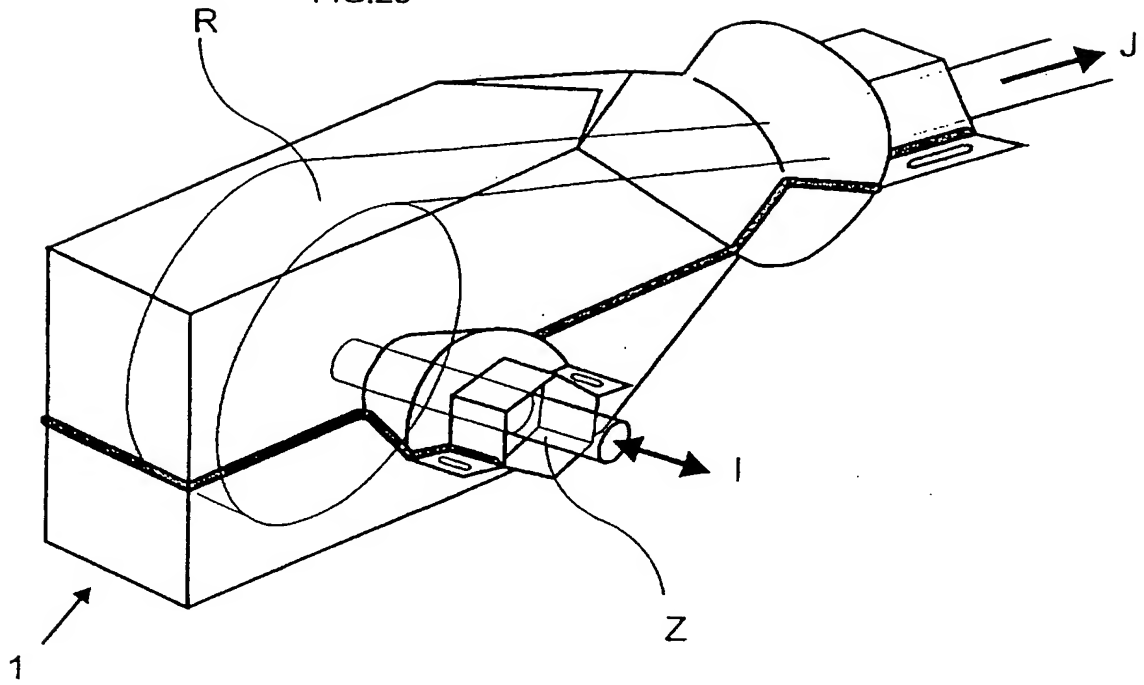
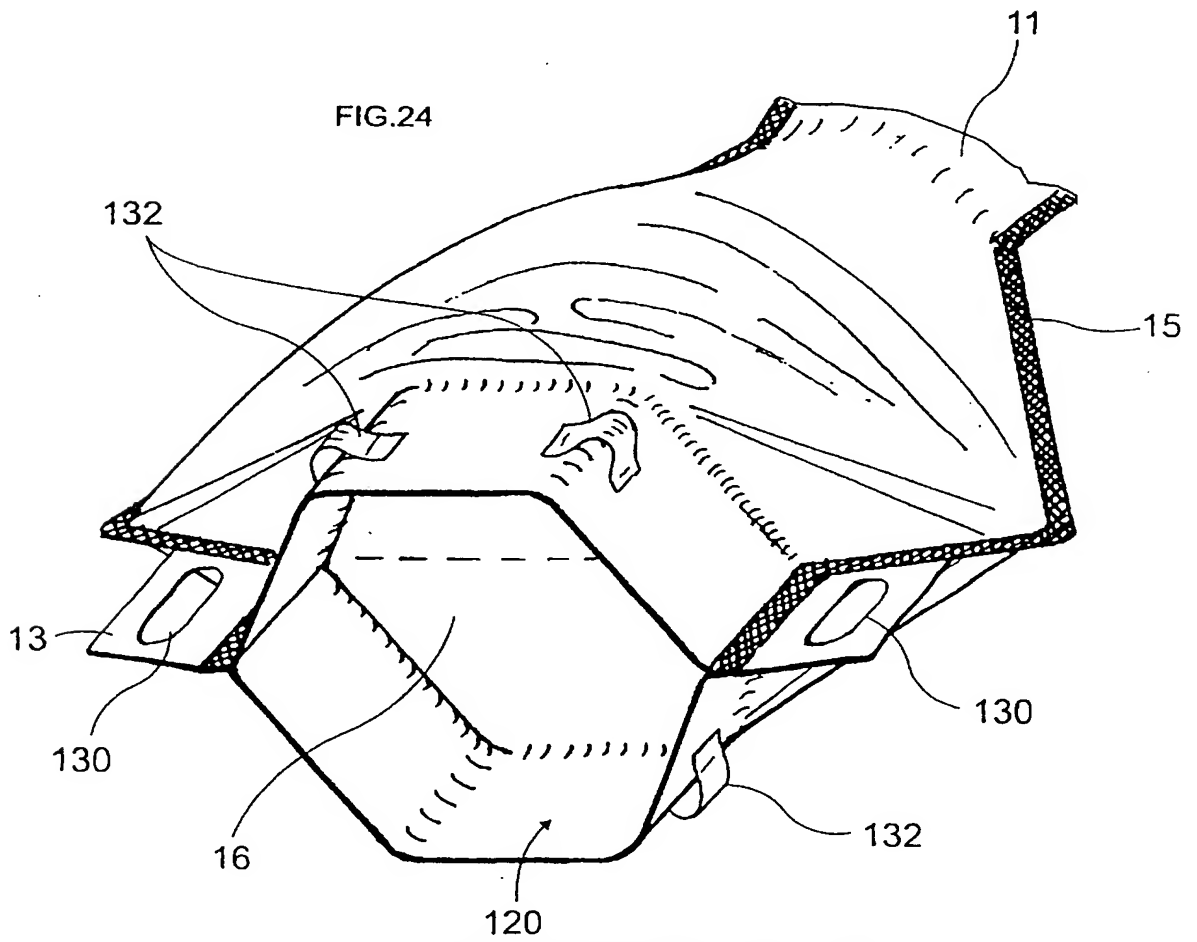


FIG.24



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12/12

FIG.25

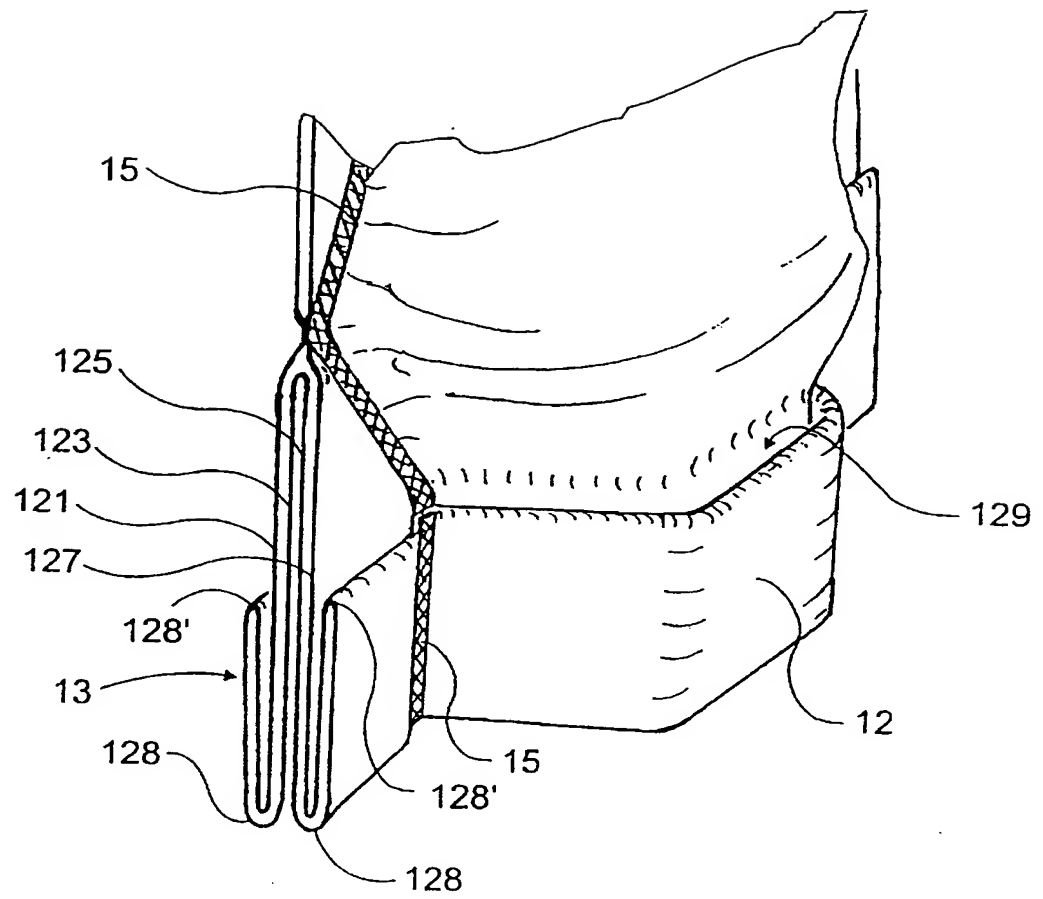
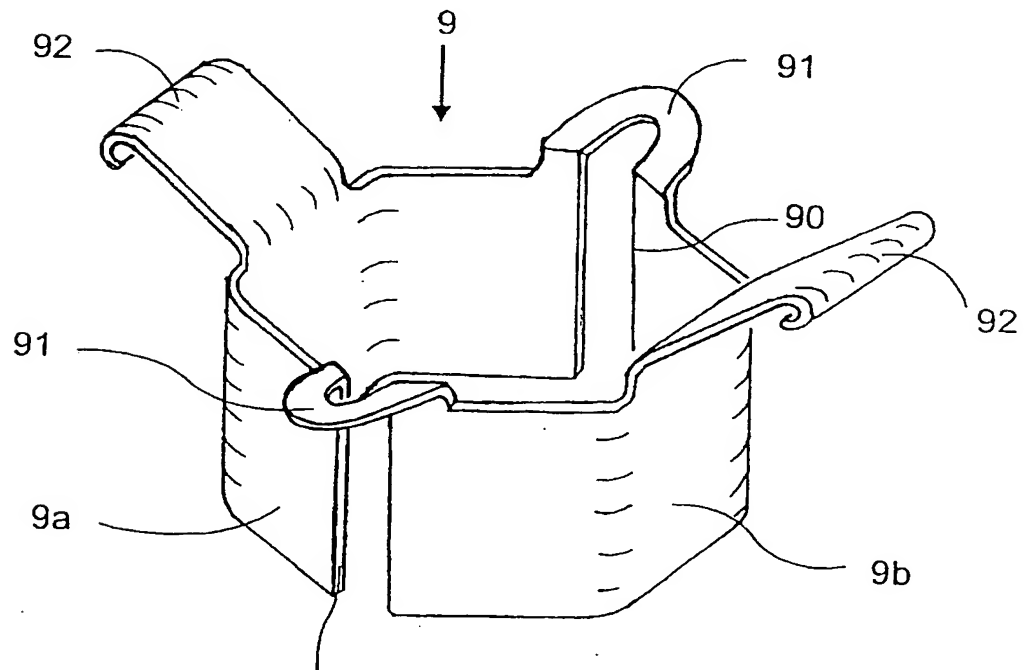


FIG.26





<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 6 B65B55/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) IPC 6 B65B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 317 908 A (NESTLEA) 31 May 1989 see column 4, line 19 - column 5, line 39; figures 1,2	1,7,10
A	---	
A	US 4 715 165 A (D. THOROGOOD) 29 December 1987 see column 2, line 51 - column 4, line 10; figures	1,10,13
A	---	
A	WO 95 03246 A (MERCK & CO) 2 February 1995 -----	
<div style="display: flex; justify-content: space-between;"> <span><input type="checkbox"/> Further documents are listed in the continuation of box C.</span> <span><input checked="" type="checkbox"/> Patent family members are listed in annex.</span> </div>		
* Special categories of cited documents :		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search  <div style="text-align: center; font-size: 1.2em;">24 March 1997</div>		Date of mailing of the international search report  <div style="text-align: center; font-size: 1.2em;">27. 03. 97</div>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. ( + 31-70) 340-2040, Tx. 31 651 epo nl, Fax ( + 31-70) 340-3016		Authorized officer  <div style="text-align: center; font-size: 1.2em;">Jagusiak, A</div>

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 96/05117

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EP 0 997 155 A1

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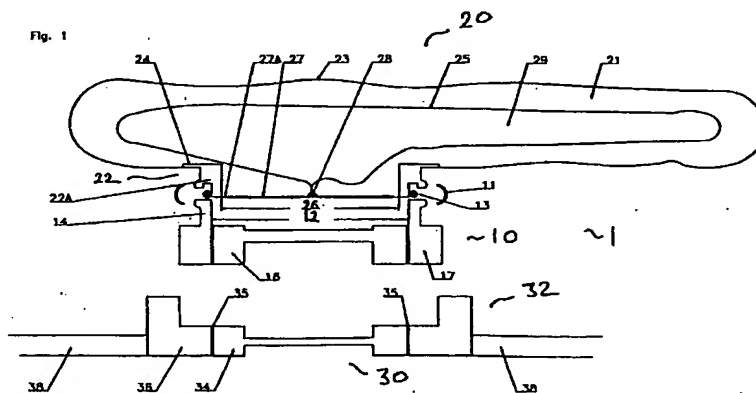
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## (54) Sterilisable container with a sterilisable adapter for docking to a port of an isolation system

(57) A sterilisable container (20) is described which includes a flexible bag (23), the flexible bag (23) having a hole in a flat portion thereof and a hollow connector port (22) fixed thereto, the connector port (22) including a collar portion (22A) and a flange portion (24) defining an internal bore (26) of the connector port (22), the inside surface of the flexible bag (23) being sealed to an outside surface of the flange portion (24) and the collar portion (22A) extending through the hole in the flexible bag (23).

Also disclosed is an adapter (10) having an internal bore (12), the connector port (22) and the adapter (10) being sealably connectable by a clamping and sealing device (11, 13) so that the internal bores (12, 16) of the connector port (22) and the adapter (10) are in open communication. Preferably, the adapter (10) has a removable door (16) sealed to the end of the adapter (10) remote from the sealable connection to the connector port (22).



EP 0 997 155 A1

## Description

[0001] The present invention relates to a sterilisable dockable bag or container which has a sterilisable connector port and a method for attaching to a standard port of a sterile enclosure or isolation system. The ports when combined may be used to transfer sterilized items from the inside of the container to the sterile enclosure or isolation system. The present invention also relates to container combination which may be docked to a standard port of a sterile enclosure or isolation system.

## TECHNICAL BACKGROUND

[0002] US 5,447,699 (Papciak) describes a combination container for holding sterilized elements and a sterilisable port. The container includes a flexible bag with a hole in it through which a collar with a flange is placed. The collar of the flange is heat sealed to the bag. The collar is sealed with a steam breathable tearable flap on its inside thus leaving a portion of the collar which is contaminated. To decontaminate this collar the port of the isolation system has piping for transferring a treatment fluid to the zone between the tearable flap and the outside of the port of the isolation system. This known bag and port suffers from the disadvantage that a sterilizing step is required after closure of the bag to the port of the isolation system.

[0003] US 5,735,609 (Norton) describes a container for holding sterilized elements. In '609 it is argued that the seal of the collar to the bag of '699 is unsatisfactory. Instead, the container of '609 includes a flexible bag having an opening which is attached to a connector port which is engageable with an isolation system. The open end of the bag is slid over the port and is clamped around the port. The open end of the bag is located in a sealing material which is fixed in a groove of the port. The sealing material may be a two-part epoxy. The front opening of the port is sealed by a door. The outer surface of this door is contaminated. The sealing arrangement of '609 is an improvement over a simple design in which the open end of a flexible bag is simply clamped to a cylinder, but the sealing material requires careful location and its curing adds an extra complication to the manufacture of the container.

[0004] It is an object of the present invention to provide a sterilisable container combination with a connector port which allows easy manufacture of the container and to provide a relatively simple method for docking the connector port to the port of an isolation system.

[0005] It is a further object of the present invention to provide a sterilisable container combination and method of connecting it to an inlet port of an isolation system which avoids complex sealing arrangements or ones which may have or develop inherent leaks.

[0006] It is still a further object of the present invention to provide a sterilisable container combination and a method of connecting it to an inlet port of an isolation

system which does not require an additional sterilization treatment when the container combination is docked to the port of an isolation system.

## SUMMARY OF THE INVENTION

[0007] The present invention includes a sterilisable container combination comprising: a container having an opening; a hollow connector port having an internal bore, the container being sealingly secured to the connector port so that the opening in the container is in registry with the bore of the connector port; an adapter having an internal bore, the connector port and the adapter being sealably connectable by a clamping and sealing device so that the internal bores of the connector port and the adapter are in open communication. Preferably the adapter has a removable door sealed to the end of the adapter remote from the sealable connection to the connector port.

[0008] The present invention also includes a plurality of sterilisable containers each having an opening and a hollow connector port having an internal bore, each container being sealingly secured to the connector port so that the opening in the container is in registry with the bore of the connector port; and a plurality of different adapters suitable for connecting to the inlet ports of different isolation systems, each adapter having an internal bore, the connector ports and the adapters being sealingly connectable by a common size of connecting and sealing devices so that the internal bores of the connector port and the adapter are in open communication.

[0009] The present invention provides a method of connecting a sterilized container to the inlet port of an isolation system, comprising the steps of: providing a container with a hollow connector port securely sealed to the container; sealingly connecting a first end of an adapter to the connector port of the container; and docking and sealing a second end of the adapter to the inlet port of the isolation system.

[0010] The present invention also includes a sterilisable container including a flexible bag, the flexible bag having a hole in a flat portion thereof and a hollow connector port fixed thereto, the connector port including a collar portion and a flange portion defining an internal bore of the connector port, the inside surface of the flexible bag being sealed to an outside surface of the flange portion and the collar portion extending through the hole in the flexible bag.

[0011] The present invention also includes a method of producing a sterilisable container, comprising the steps of: providing a flexible sheet enclosure with a flat portion; providing a hole in the flat portion of the flexible sheet enclosure and fixing a hollow connector port thereto, the connector port including a collar portion and a flange portion defining an internal bore of the connector port, and sealing the inside surface of the flexible sheet enclosure to an outside surface of the flange por-

tion, the collar portion extending through the hole in the flexible sheet enclosure. The enclosure may extend in one direction to form the container and the sheet material forms the walls of the container the flat portion being provided by a front face of the sheet enclosure perpendicular to the extension direction of the container and the hole is provided in the front face.

[0012] The present invention also includes a sterilisable container device comprising a first outer container and an inner flexible container, the outer container including a hollow connector port, the connector port being sealed by a removable cover; and the removable cover including a holding device for the inner flexible container on the side of the cover facing towards the inner flexible container.

[0013] The dependent claims define further individual embodiments of the present invention. The present invention, its advantages and embodiments will now be described with reference to the following drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

### [0014]

Fig. 1 is a cross-sectional schematic representation of a container combination in accordance with a first embodiment of the present invention.

Fig. 2 is a schematic general view of the container combination of Fig. 1.

Fig. 4 is a schematic representation of various designs of container combinations in accordance with the first embodiment.

Fig. 5 is a cross-sectional schematic representation of a container combination in accordance with a second embodiment of the present invention.

Fig. 6 is a schematic cross-sectional representation of a connector port in accordance with one embodiment of the present invention.

Fig. 7 shows use of a connector port according to another embodiment.

Figs. 8 to 11 show steps in the formation of a flexible sheet enclosure with a port perpendicular to the plane of the sheet material of the type shown schematically in Fig. 4E.

Fig. 12 is a schematic cross-section through a part of the flexible sheet container shown in Fig. 11.

Fig. 13 is a schematic view of the completed sheet enclosure described with reference to Figs. 8 to 12.

Fig. 14 is an isolation room in accordance with another embodiment of the present invention constructed from two flexible containers as shown in Fig. 13

## DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

[0015] The present invention will be described with reference to certain embodiments and to certain draw-

ings but the invention is not limited thereto but only by the claims.

[0016] Fig. 1 is a schematic cross-sectional view through a sterilisable container combination 1 in accordance with a first embodiment of the present invention and a port 32 of a standard isolation system 30. Fig. 2 is a schematic view of the combination 1. The combination 1 comprises three main pieces: a reusable adapter 10, a connector port 22 and a container 20. The adapter 10 is sealably connectable to the connector port 22 and is adapted to fit to the standard port 32 of the isolation system 30. The connector port 22 includes a collar 22A with a flange 24 and an internal bore 26 and the container 20 includes a flexible bag 23 which is sealed to the flange 24. Optionally, the collar 22A may be sealed by a tearable or peelable flap or cover 27. It is preferred if the cover 27 is located at, on or immediately adjacent to the lip of the collar 22A which faces away from the bag 23 (as shown in Fig. 1) but the present invention is not limited thereto. The bag 23 may be open at one end to allow inclusion of sterilized or sterilisable objects or a second inner bag 25 and is preferably closable, e.g. by heat sealing.

[0017] Optionally, container 20 may also include a second inner bag 25 which may be optionally and releasably attached to an inside bag holding device 28 on the flap or cover 27. The adapter 10 is in the form of a ring 17 defining an internal bore 12, the ring 17 having a portion 14 for sealable connection to the collar 22A of the container 20. The sealable connection between the collar 22A and the adapter 10 may be completed by a clamp 11 and a seal 13, e.g. a rubber "O" ring. Ring 17 and collar 22A are typically circular in cross-section but the present invention is not limited thereto.

[0018] Various materials may be used for making the bag 23 depending upon the application and its requirements. It is preferred if the bag 23 may be made of a single material such as low density polyethylene, high density polyethylene or polypropylene which allows the bag to be recycled, however, it is not always possible to use only a single material. Laminates including inner nylon or aluminum layers may be used and preferably such laminates have an outer thermally sealable layer such as low density or high density polyethylene. The bag 23 may also be made of a breathable material or include breathable sections or patches. A suitable breathable material is Tyvek™ which allows steam to pass through and to sterilize the inside volume 21 and contents of the bag 23. The inner bag 25 having an inner volume 29 may be made of any of the materials described above for the outer bag 23. The inner bag 25 may be open at one end to allow inclusion of sterilized or sterilisable objects and can then be closed by heat sealing. For example, the inner bag 25 may be held by the holding device 28 to the optional flap or cover 27, e.g. heat sealed with a seal (28) or releasably clamped with a mechanical clamp (28). The inner bag may have a long tubular neck (best shown in Fig. 3) which can be

drawn through the connector port 20 and be used as a pipe for dispensing the materials from inside inner bag 25. To allow removal of cover or flap 27, a circumferential mechanical weakness 27A may be provided. Cover or flap 27 may be made of a tearable or peelable breathable material such as Tyvek™. Preferably, the cover or flap is removable from the side remote from the bag 23, i.e. access is possible from the isolation system 30.

[0019] The bag 23 is preferably sealed to the connector port 22 by heat sealing or any other similar method which provides a high quality hermetic seal. Preferably, the connector port 22 is in the form of a rigid collar 22A with a flange 24. This collar 22A is placed inside the bag 23 and located through a hole therein so that the outer surface of the collar 22A comes in contact with the inner surface of the bag 23. The inner side of the bag material which overlaps the flange 24 is sealed to the outer surface of the flange 24. The collar 22A is preferably made from a material which is heat sealable to the material of bag 23. Suitable materials are, for instance, low density, high density polyethylene or polypropylene. By heat sealing the inside of the bag 23 to the outside of the flange 24 one of the difficulties with the seal of '699 is solved. Whereas the bag to collar seal of '699 tends to peel and open when a load is placed on the bag, the seal of the present invention is much more robust and does not tend to peel when the bag 23 is loaded.

[0020] Collar 22A in accordance with an embodiment of the present invention is shown schematically in cross-section in Fig. 6. Collar 22A is generally cylindrical in shape, e.g. circular, square, hexagonal, and includes a first cylindrical portion 221 which is preferably formed integrally with the flange 24. The other end of the first cylindrical portion 221 is terminated by a raised bulbous ring 222 which co-operates with a similar ring 10A on adapter 10 to form a suitable outer mating surface for the clamp 11 when applied. An annular recess 223 is preferably provided in the end surface of the bulbous ring 222 for receipt of a seal 13, e.g. an "O" ring. A second short cylindrical portion 224 is preferably formed integrally with the bulbous ring 222, the first cylindrical portion 21 and the flange 24. The second cylindrical portion 224 has an outer diameter which is smaller than the inner diameter of the recess 223 and the internal diameter of the adapter 10, and is preferably sealed by a tearable or peelable cover film 27 on or adjacent its outer lip. Film 27 may allow passage of sterilizing fluids, e.g. of Tyvek™. Cover 27 may include mechanical weaknesses 27A for assisting in the tearing thereof. Further, film 27 may be provided with a pull-ring 225 which eases tearing or peeling film 27. Film 27 may include an inner bag holding device 28 on its inside (shown here as a clip).

[0021] As shown best in Fig. 2, the edges of bag 23 are preferably provided with reinforcing 39 and with attachment or lifting holes and/or tabs 37 to improve handling. Sealingly connected to the connector port 22

is an adapter 10. This adapter 10 is designed so that its end 17 remote from the connector port 22 fits into a standard port 32 of an isolation system 30. Hence, adapter 10 adapts the connector port 22 to the dimensions of the standard inlet port 32 of the isolation system 30. Preferably, the adapter 10 is reusable. The combination of the bag 23 and the connector port 22 may be reusable but it is normally more economic to recycle the material rather than reuse the combination 22, 23. Important advantages of the adapter 10 and the collar 22A are that the inner bore of the adapter 10 is sterilisable before the adapter 10 is docked to the inlet port 32 of the isolation system 30 and that standard bags 23 and connector ports 22 can be produced and the necessary re-usable adapters 10 fabricated to adapt the standard collars 22 to the inlet opening 32. This reduces inventory and unit cost. Adapter 10 may be made from any suitable material which meets the requirements of the particular application. Typically the adapter 10 will be made of metal or more preferably a plastic material such as polypropylene, high density polyethylene, PTFE, polycarbonate or Lexan™. An end portion 14 of the adapter 10 remote from the portion 17 is configured to provide a sealing connection to the connector port 22. For example, the adjacent end surfaces of the connector port 22 and the end portion 14 of the adapter 10 may be configured to provide an "O" ring seal using a rubber "O" ring 13 and a metal clamp 11. The metal clamp 11 is applied to standardized dimensions on the outside of the collar 22A and the adapter end 14, therefore the clamping effect is reliable and repeatable.

[0022] The adapter 10 is configured to fit the standard inlet opening 32 of the isolation system 30. As one possible configuration, the end opening 12 of the adapter 10 is preferably sealed by a door 16 which may be sealed to the inner bore of adapter 10. On the end surface of the door 16 an aggressive pressure sensitive adhesive 18 may be applied and protected by a release paper (not shown). In the inlet port 32 of the isolation system 30 there may be a corresponding door 34 located in a housing 36 and provided with a hermetic seal 35 between the door 34 and the housing 36. The housing 36 is located in the wall 38 of the isolation system 30. The housing 36 has internal dimensions which allow receipt of the adapter 10.

[0023] Alternative shapes of container 20 are shown schematically in Fig. 4A to 4E. Figs. 4A to D show lay flat flexible bags 23 with the connecting ports 22 arranged in various positions. Fig. 4E shows a modified flexible bag 23 including a front face perpendicular to the main lay-flat bag 23 in which the connecting port 22 is sealed. A method of manufacturing this container 20 will now be described.

[0024] As shown in Fig. 8 a flat piece of sealable flexible material is folded in two to form two sheets 65, 66 on top of each other and a fold 67. A half-circular opening 68 is cut out of a portion of the fold 67 of the material. Reference numbers 71, 72 represent the fold

ends where the half-circle 68 cuts the fold 67. Reference numbers 71A, 72A represent the extreme fold ends on the outer edge of the sheet material. As shown in Fig. 9 the folds 67, 68 are formed into tucks 73, 74 by tucking ends 71 and 71A and 72 and 72A into the space between the two sheets 65, 66 to form one tuck 73, 74 on each side of the opening 68 respectively. Each tuck 73, 74 has an upper fold 75, 76, respectively which is a part of the folds 67, 68, respectively but with the fold in the opposite direction. First seals 77, 78 and 79, 80 are formed on each of the tucks as best shown in Fig. 10 by placing a heat-resistant material inside the tucks 73, 74 or by treating the inside mutually opposing surfaces of each tuck 73, 74 to make these surfaces non-sealable. A V-shaped sealing structure is formed in the sheets 65, 66 as shown in Fig. 10. The first seals 77-80 may be thermal welds or heat seals. A section through the fold ends 71, 72 is shown in Fig. 12. As can be seen, four seals 77-80 are formed with the folds 75, 76 lying between. In addition second seals 81, 82 are formed between sheet materials 65, 66. By trimming away excess sheet material from the seals 77-82 a flexible sheet container 70 is formed as shown in Fig. 11. This container 70 may be opened-out in the form of a truncated cone-shaped structure with an opening 68 at its smallest end. Following an edge of the sheets 65, 66 there is a seal 81 between the two sheets 65, 66. This seal 81 merges into two seals 77, 78 which define the tuck 73. Seals 77, 78 merge into folds 83, 84 which terminate at the opening 68. The other edge of the flexible sheet container 70 is similar. A connector port 22, preferably of circular cross-section, with a collar 22A having a flange 24 and an internal bore 26 is now pushed into the opening 68 from the within the cone-shaped structure as shown in Fig. 13. Due to the construction of the cone-shaped structure as explained above a flat portion 85 of sheet material lies snugly against the outer surface of the flange 24 so that an inner surface of the flat portion of the sheet material is in contact with the outer surface of the flange 24. This flat portion 85 does not contain any welds or seals or double thicknesses of sheet material. Hence, this flat portion 85 may be easily sealed to the flange 24, e.g. by heat sealing. The connector port 22 may be provided with a portion for sealable connection to an adapter 10 using a seal such as an "O" ring 13 and a clamp 11 as has been described above. The port 22 may include a cover 27 as described with reference to any of the embodiments of the present invention. In particular the cover 27 may include an inside bag holding device 28 as described with reference to any of the embodiments of the present invention. An inside bag 25 may be installed from the open end of container 70 and secured to holding device 28. The device of Fig. 13 is particularly suited for the transfer of bulky items which cannot pass a 90° bend as present in the containers shown in Figs. 4A to D, for example.

[0025] Fig. 14 shows how the device of Fig. 13 may

be assembled into a temporary isolation room 90. Two devices as shown in Fig. 13 are sealed together at the openings remote from connector port 22. Glove ports 92, 94 may be provided in the temporary isolation room 90. Each of the connector ports 22 is now fixed to the communication port of another device, e.g. another container or to the communication port of a fixed isolation area using an adapter 10 as described above. Items may now be transferred from a container into the temporary isolation room 90. Here they may be manipulated through the glove ports 92, 94. The items may now be returned to the container from which they came, transferred to another container or transferred to an isolation area depending on what is connected to the connector ports 22 of the temporary isolation room 90.

[0026] Figs. 5A to D show various schematic ways of forming the cover 27 on the outer opening of the connecting port 22 any of which may be used with any of the embodiments of the present invention. In Fig. 5A a cover 27 is provided with an annular mechanical weakness 27A as has already been described with respect to Fig. 1. Cover 27 may optionally be provided with an inner bag mechanical holding device 28 or a plug 28 of material for welding and for holding an inner bag 25. Fig. 5B shows an alternative embodiment of the cover 27 in the form of a cap. This cap 27 may be used as an alternative to cover 27 of Fig. 5A or in addition thereto, especially as a mechanical protection for the cover 27 of Fig. 5A. Cap 27 extends over and seals off the outer opening of the collar 22A. The inner diameter of cap 27 may be an interference fit with the outer diameter of collar 22A or may be heat sealed to the end thereof. When cap 27 is used without an inner cover 27 as shown in Fig. 5A it may include an inner bag fixing means 28 on its inside, e.g. a clip.

[0027] Fig. 5C shows a further embodiment of the cover 27 which may be used as an alternative to cover 27 of Fig. 5A and may be used with or without the cover 27 of Fig. 5B. A peelable cover 27 is peelably and sealably fixed to the outer surface of the collar 22A. Peelable cover 27 may include any of the inner bag fixing devices 28 mentioned for the previous embodiments. Fig. 5D shows a further flexible cover 27 which is an alternative to any of the covers 27 shown in Figs. 5A to D or may be used in addition thereto. Flexible cover 27 extends over the outer opening of the collar 22A so that it not only can seal off this opening but also protects the sealing surfaces of collar 22A from contamination during transport. The inner diameter of the flexible cover 27 may be an interference fit with the outer diameter of collar 22A or may be peelably or tearably sealed to the outside of bag 23 on flange 24. Flexible cover 27 may include on its inner side any of the inner bag fixing means 28 described with respect to the previous embodiments as shown in any of Figs. 5A to C.

[0028] The container combination 1 of the present invention may be used in several different ways. Firstly, the connector port 22 are installed in the bag 23 and the

collar 22A is inserted through the hole in bag 23. The inner side of the bag 23 overlapping the flange 24 is heat sealed thereto. One or more of the covers 27 of Figs. 5A to D may then be attached to collar 22A. Alternatively, the cover 27 may be attached to the collar 22A before the flange 24 is sealed to the inside of the bag 23. The inner bag 25 may be introduced into bag 23 and be fixed to one of the covers 27 using one of the inner bag holding devices 28 described with respect to Figs. 5A to D and then filled with items to be sterilized and sealed. The outer bag 23 may be sealed at the same time. The adapter 10 is then sealably fixed to the connector port 22 using seal 13 and clamp 11. The complete container combination 1 now appears as in Fig. 2. The container combination 1 is then sterilized by gamma radiation, ethylene oxide or steam as appropriate. Where steam or gas is used, it is preferred if suitable patches of breathable material are provided such as Tyvek™ to allow penetration of the sterilizing fluid. In particular, it is preferred if cover or flap 27 is made from a breathable material such as Tyvek™ and/or similar patches are provided on bag 23. In this case the inner bore of the connector port 22 as well as the back surface of door 16 is sterilized. Alternatively, cover or flap 27 may be omitted leaving a simple opening 26. Once the complete container combination 1 is sterilized it may be checked by quality control and shipped to the isolation system 30. As is known to the skilled person standard inlet ports 32 usually have quick fastening and locking system to provide a secure hermetic seal. Such an inlet port is supplied by la Calhène, Vélizy, France. The adapter 10 is attached to the port 32 and the contaminated sides of doors 16 and 34 fixed together (e.g. by the pressure sensitive adhesive on door 16) to trap any contamination. The combination of doors 16 and 34 is now broken away and removed to the inside of the isolation system 30. Now the cover or flap 27 (if present) is removed towards the isolation system 30 pulling the inner bag 25 with it. The inner bag 25 is then pulled at least partly into the isolation system 30 and its contents removed and a new door 34 sealed to the housing 36. Now the empty container combination 1 may be removed and the bag 23 and collar 22A separated from the adapter 10 by releasing the clamp 11.

[0029] An alternative way of using the present invention is to supply the container 20 having the connecting port 22 already attached and sealed by one or more of the covers 27 described with reference to Figs. 5A to D. The bag 23 is open along one side. The bag 23 is filled through this opening and this opening is then sealed, e.g. by heat sealing. A cover 27 in accordance with Fig. 5E is applied to keep the sealing surface of the collar 22A free of contamination. Now the container 20 and its contents can be sterilized by any suitable method. The filled container 20 is then shipped to the location of the isolation port 32. In a suitable clean room the outer cover 27 may be removed and the collar 22A attached to a sterilized adapter 10 and sealed and

clamped with the seal 13 and clamp 11. Now the complete combination 1 can leave the clean room if required before being docked to an isolation port 32 and the contents of bag 23 transferred through the adapter 10 and the connector port 22.

[0030] In the above only two methods of using the present invention have been described. However, the present invention as described has such flexibility that many ways may be devised for transferring sterilized materials using the components described above, all of which are included as embodiments of the present invention.

[0031] While the invention has been shown and described with reference to preferred embodiments, it will be understood by those skilled in the art that various changes or modifications in form and detail may be made without departing from the scope and spirit of this invention as defined in the claims.

[0032] For example, the present invention has been described with reference to flexible bags 23, 25, however, the invention is not limited thereto. As an example, Fig. 3 shows a cross-sectional schematic representation of a second embodiment of the container combination 1 of the present invention. It includes a rigid blow-molded canister 43 which has a connector port 42 formed on one end. Connector port 42 has an integral shaped collar section 42A which co-operates with an "O" ring seal 13 and a clamp 11 to form a sealed connection to an adapter 10. The canister 43 may contain an inner flexible bag 45 attached to a flap or cover 47 by means of an inner bag holding device 28 as described with respect to the first embodiment. Inner flexible bag 45 may have a long narrow neck portion 45A which may be drawn through the connector port 42 and used as a discharge tube for items in the inner bag 45. Cover 47 may be similar in form and function to any of the covers 27 described with reference to Fig. 5A to D. Cover 47 may be, for example, peelable or include a mechanical weakness 47A which allows removal of a central portion of the flap or cover 47 by tearing. The canister 43 when sealably connected to the adapter 10 by means of a seal 13 and clamp 11 forms a container combination 1 in accordance with the present invention and may be used as generally described for the first embodiment.

[0033] Further, the present invention includes manufacturing a plurality of similar or different bags 23 or canisters 43 and providing each with a connector ports 22, 42 respectively having a standard connecting structure and dimensions to fit to adapters 10. Further a plurality of adapters 10 may be provided, each adapter 10 having on one end the structure and dimensions necessary to fit to one of the inlet openings 32 of a commercially available isolation system 30. The other end of the adapter 10 has a standard structure and dimensions to form a hermetic sealing connection with the connector ports 22, 42 of a container combination 1 according to the present invention.

[0034] In addition, the present invention is not limited



ited to use of an adapter 10. A further embodiment of the present invention is shown schematically in cross-section in Fig. 7. The collar 22A and its attachment to the outer bag 23 is generally as described with respect to the previous embodiments (or may be a collar 42A of a container 40) and in particular is similar to that shown in and described with reference to Fig. 6 except without the pull-ring 225. The outer lip of the second cylindrical portion 224 of the collar 22A is sealed with a breathable or a non-porous film or cover 27. An isolation port 32 of an isolation system 30 is initially sealed by a sterilized film 55 which is drawn from a roll 57 of such material in a sterile box 59. Sterile box 59 may be kept sterile by various means including heaters 56. The film 55 is removably sealed to the outer rim of the port 32 by means of seals 58 and releasable clamps (not shown for clarity purposes). Both the collar 22A and the isolation port 32 are preferably rectangular in cross-section, but the present invention is not limited thereto. Preferably, the container 20, 40 is delivered to the isolation port 32 with the insides of bag(s) 23 and 25 (if present) sterilized as has been described above. Inner bag 25 (if present) is preferably attached to the inner bag holding device 28, e.g. by a clip. The film cover 27 and the collar 22A may be protected by a cap as shown in, and described with respect to Fig. 5D. Just before docking to port 32, this outer cap is removed and collar 22A is sealingly clamped in close proximity to the sterilized film 55 by clamps (not shown for clarity reasons) which locate and seal onto the bulbous ring 222 and/or the outer diameter of the second cylindrical portion 224 of the collar 22A and/or onto an "O" ring in the annular recess 223. One way of doing this is to form the adapter 10 of Fig. 1 (without the door 16) integrally with isolation system 30 so that once the clamp 11 has been applied, the container 20, 40 is sealed and clamped to the isolation system 30. Moveable heat sealers 51 and 52 including hot knives 53, 54 respectively, are now brought against the side of the film 55 towards the isolation zone 30 and the outer edge of a central portion of cover film 27 is heat sealed to the film 55 thus trapping any contamination therebetween as well as optionally, heat sealing the film 55 to the end surface of the second cylindrical portion 224. Also the knives 53, 54 cut through (e.g. melt through) the films 55 and 27 thus opening the container 20. The combined films 27, 55 are now drawn into the isolation system 30 pulling with them the long narrow tubular neck (shown best in Fig. 3, 45A) of the inner bag 25 if present. The contents of bag 23 and/or inner bag 25 may now be removed. The clamps on seals 58 are released and film 55 is cut through by knife 60. The piece of film 55 attached to the outer rim of second cylindrical portion 224, bag 25 (if present) and the cut and sealed pieces of film 27, 55 are now pushed back into the container 1. The opening 32 is now resealed by drawing a further piece of film 55 across the opening 32 from roll 57 and sealing the film 55 thereto by clamping onto the seals 58. Now the sealing clamps on the ring

222 may be released and the container 1 discarded.

[0035] The container combinations 1 of the present invention provide the advantage that standard bags and canisters 23, 43 and standard connector ports 22, 42 may be used and, by use of a reusable adapter 10, these may be adapted to the various types of inlet ports of isolation systems which are available on the market or may yet be developed. One aspect of the present invention is to provide a standard sealing and connection interface between the adapters 10 and the connector ports 22, 42. The present invention also allows the double security of an inner and outer bag or canister. A simple reliable means of sealing the flexible outer bag to the flange of the collar 22A is also provided. Further, by making the cover or flap 27, 47 breathable, the inner surface of the adapter can be sterilized before the container combination 1 is shipped thus avoiding an additional sterilizing step after the adapter 10 has been fixed to the inlet port of the isolation system. By attaching an inner bag 25, 45 to the flap or cover 27, 47 which is removable in the direction of the isolation system 30, the inner bag 25, 45 may be easily emptied into the isolation system 30 while still being in a sealed state. This provides not only ease of handling but also improved cleanliness.

#### Claims

##### 1. A sterilisable container combination comprising:

an outer container having an opening;  
a hollow connector port having an internal bore, the outer container being sealingly secured to the connector port so that the opening in the outer container is in registry with the bore of the connector port; and  
an adapter having an internal bore, the connector port and the adapter being sealably connectable by a clamping and sealing device so that the internal bores of the connector port and the adapter are in open communication.

##### 2. A container combination according to claim 1, wherein the adapter has a removable door sealed to the end of the adapter remote from the sealable connection to the connector port.

##### 3. A sterilisable container device comprising:

an outer container and an inner flexible container, the outer container including a hollow connector port, the connector port being sealed by a removable cover; and  
the removable cover including a holding device on the side of the cover towards the inner flexible container for holding the inner flexible container.

4. A container combination according to claim 1 or 2 or a container device according to claim 3, wherein the outer container is a flexible bag.
5. A container combination or a container device according to claim 4, wherein the flexible bag has a hole in a flat portion thereof and the connector port includes a collar portion and a flange and an inside surface of the flexible bag is sealed to an outside surface of the flange.
6. A sterilisable container device comprising:
  - a flexible bag, the bag having a hole in a flat portion thereof and a hollow connector port fixed thereto, the connector port including a collar portion and a flange, and an inside surface of the flexible bag being sealed to an outside surface of the flange.
7. A container combination according to any of claims 1, 2, 4 or 5 or a container device according to any of claim 6, wherein the connector port has a removable cover.
8. A container combination according to any of claims 1, 2, 4, 5 or 7, or a container device according to claim 6 or 7, further comprising an inner flexible bag within the container.
9. A container combination or a container device according to claim 8, wherein the inner bag is attached to the removable cover.
10. A container combination or a container device according to claim 8 or 9, wherein the removable cover includes an inner bag holding device.
11. A plurality of container devices, each having an opening and a hollow connector port having an internal bore, each container device being sealingly secured to the connector port so that the opening in the container is in registry with the bore of the connector port; and a plurality of different adapters suitable for connecting to the inlet ports of different isolation systems, each adapter having an internal bore, the connector ports and the adapters being sealingly connectable by a common size of connecting and sealing devices so that the internal bores of the connector port and the adapter are in open communication.
12. A method of connecting a sterilised container to the inlet port of an isolation system, comprising the steps of: providing a container device with a connection port securely sealed to the container device; sealingly connecting a first end of an adapter to the connector port of the container device; and docking and sealing a second end of the adapter to the inlet port of the isolation system.
13. The method according to claim 12, wherein the container device is a container device according to any of claims 3 to 10.
14. A method of producing a sterilisable container, comprising the steps of:
  - providing a flexible sheet enclosure with a flat portion;
  - providing a hole in the flat portion of the flexible sheet enclosure and fixing a hollow connector port thereto, the connector port including a collar portion and a flange portion defining an internal bore of the connector port, and sealing the inside surface of the flexible sheet enclosure to an outside surface of the flange portion, the collar portion extending through the hole in the flexible sheet enclosure.
15. The method according to claim 14, wherein the enclosure extends in one direction to form the container and the sheet material forms the walls of the container the flat portion is provided by a front face of the sheet enclosure perpendicular to the extension direction of the container and the hole is provided in the front face.

Fig. 1

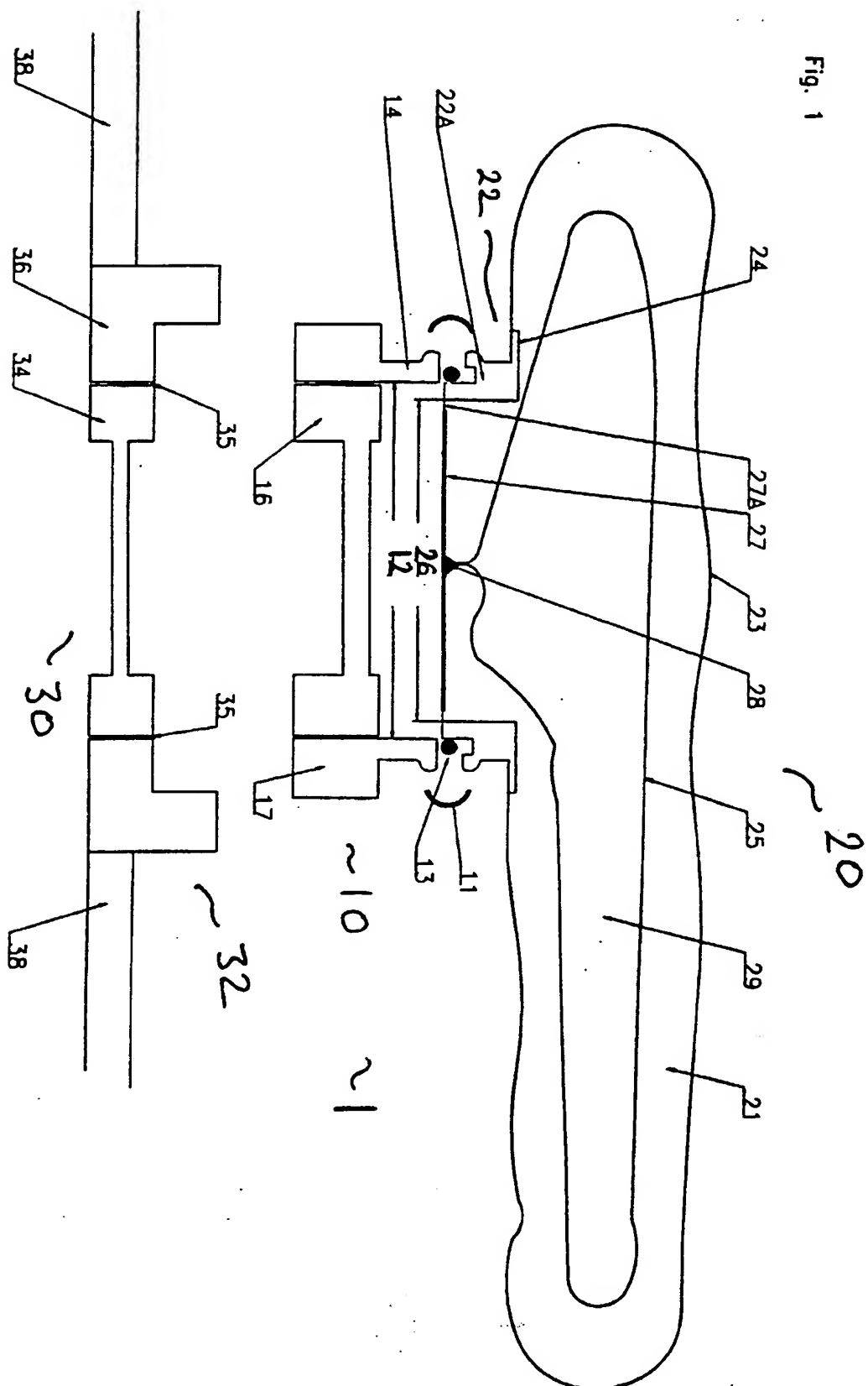
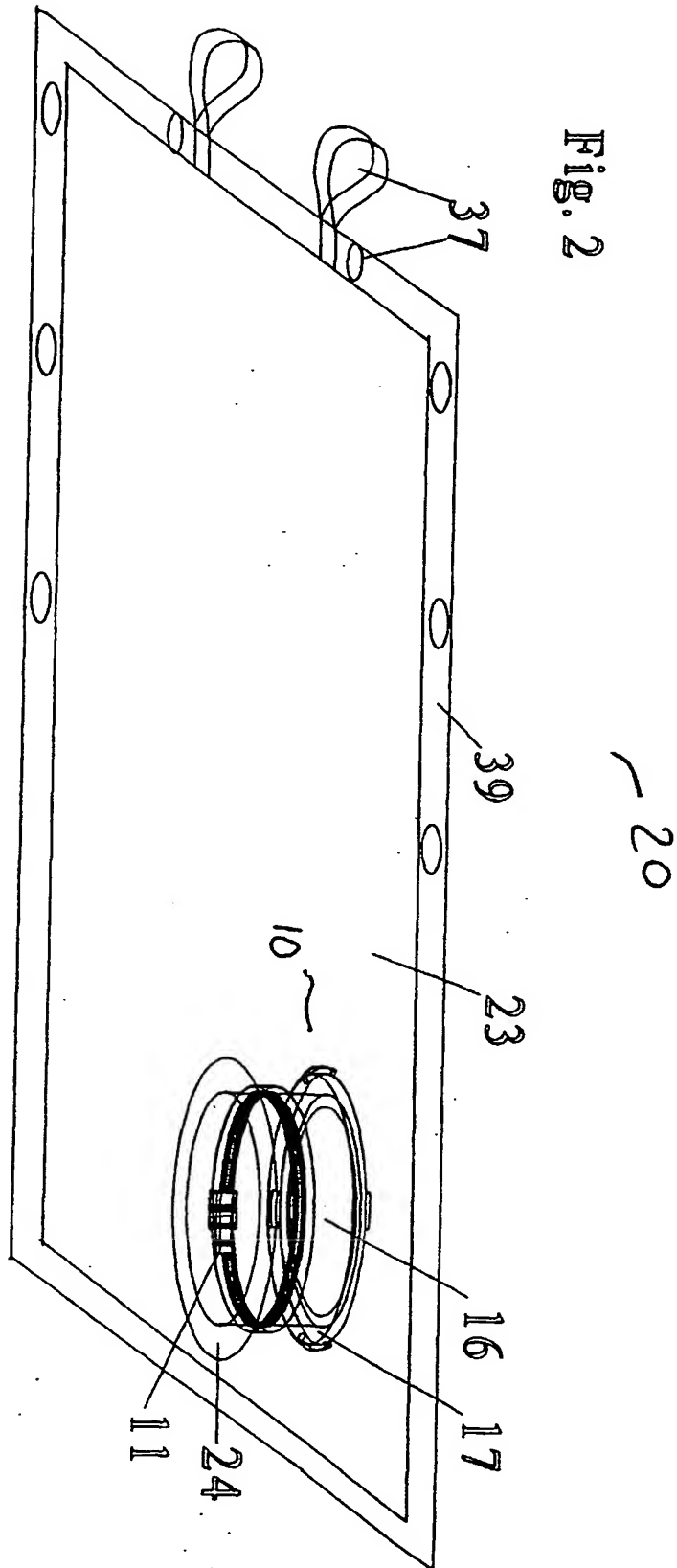
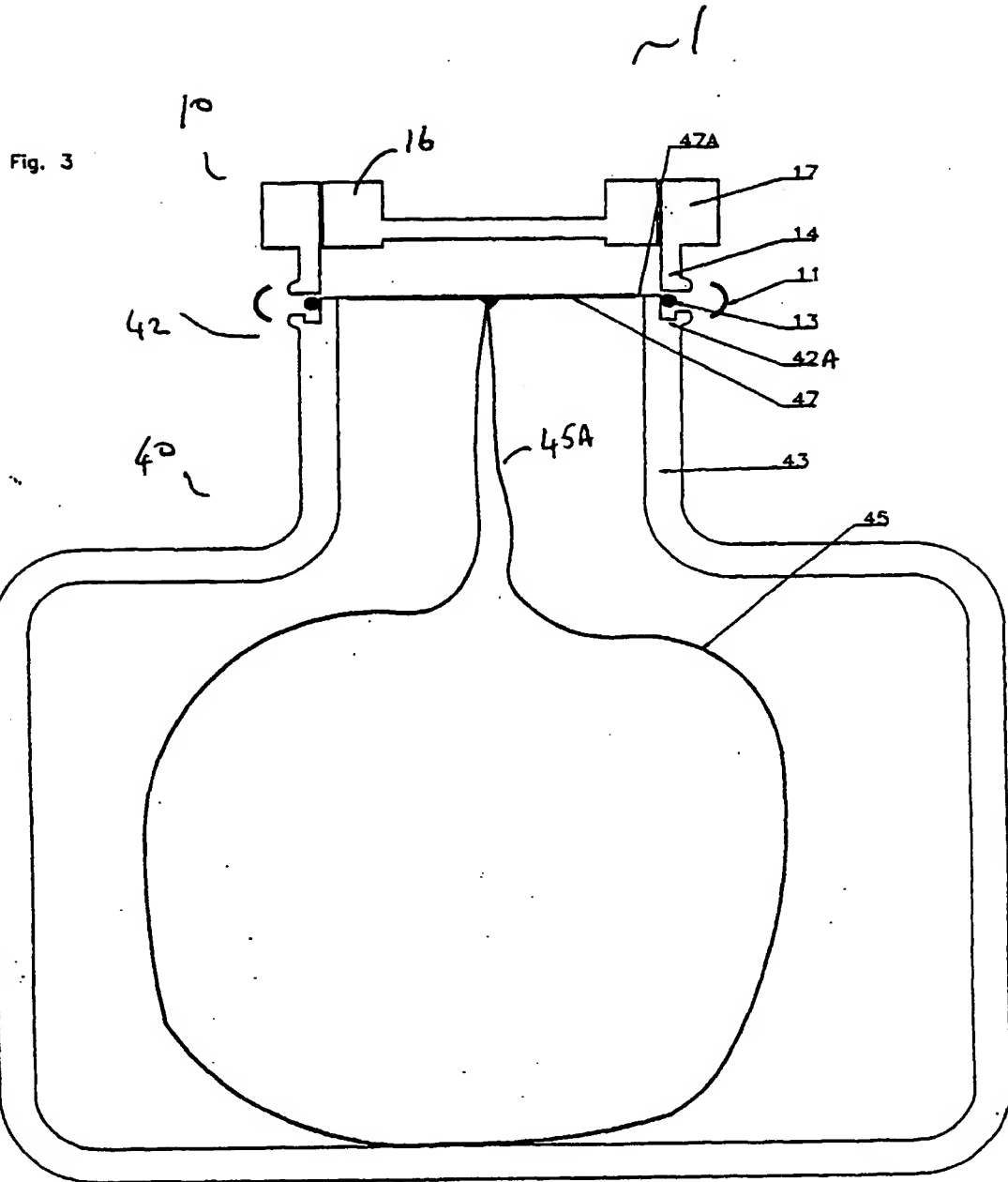


Fig. 2





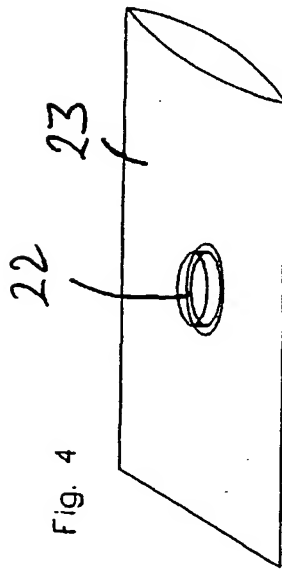


Fig. 4A

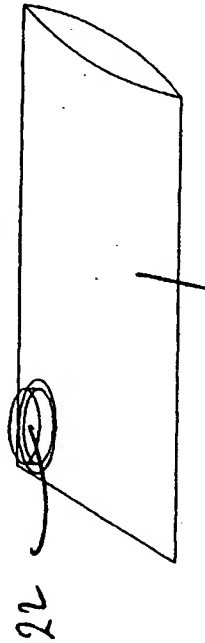


Fig. 4B

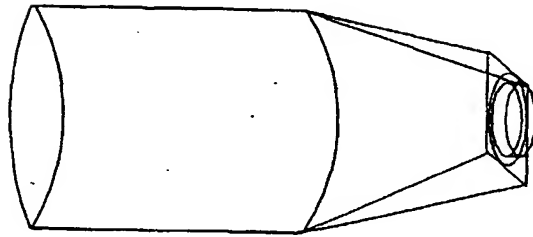


Fig. 4C

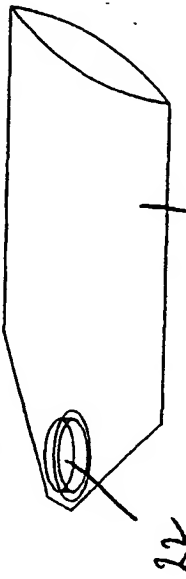
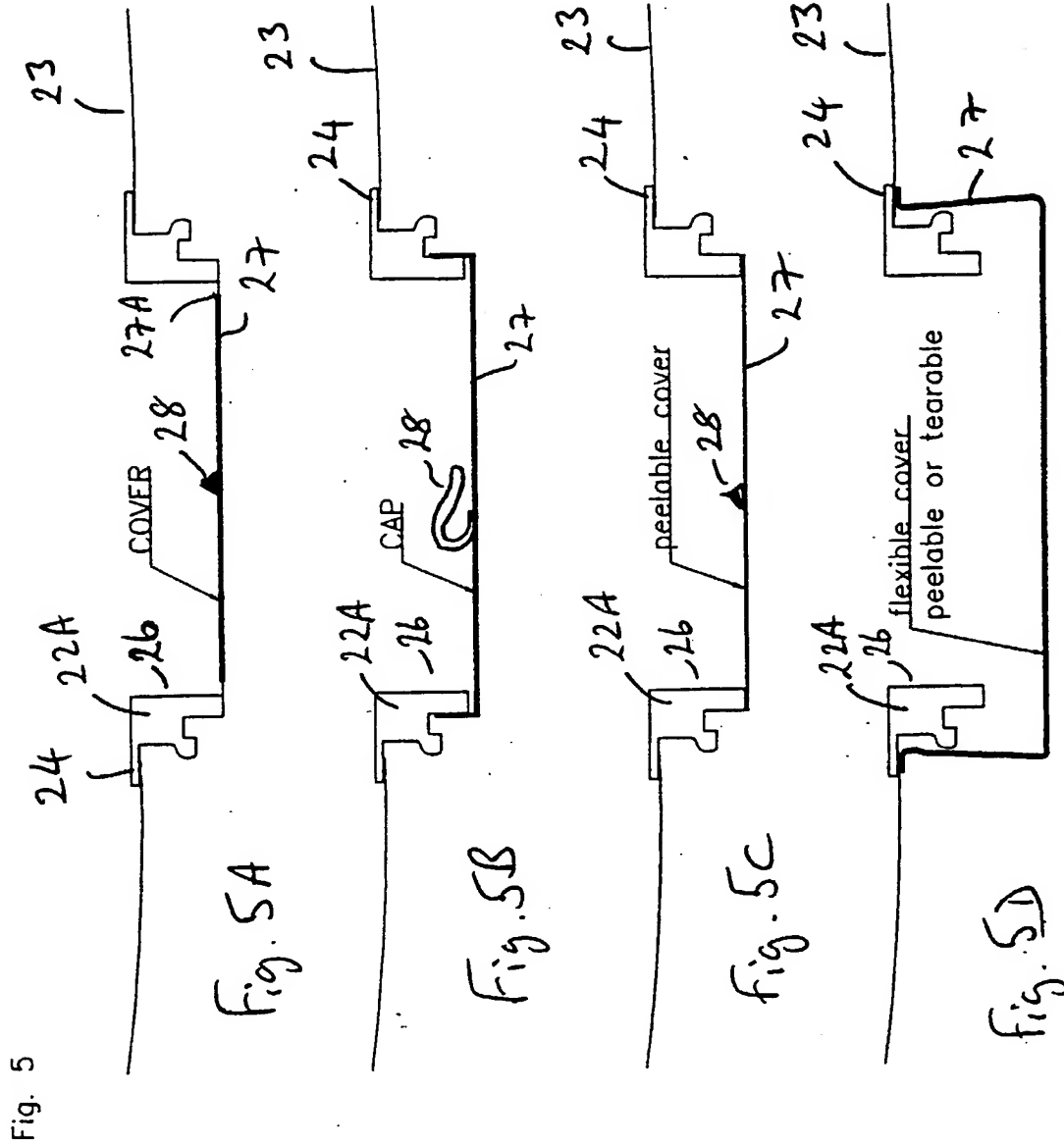


Fig. 4E

Fig. 4D



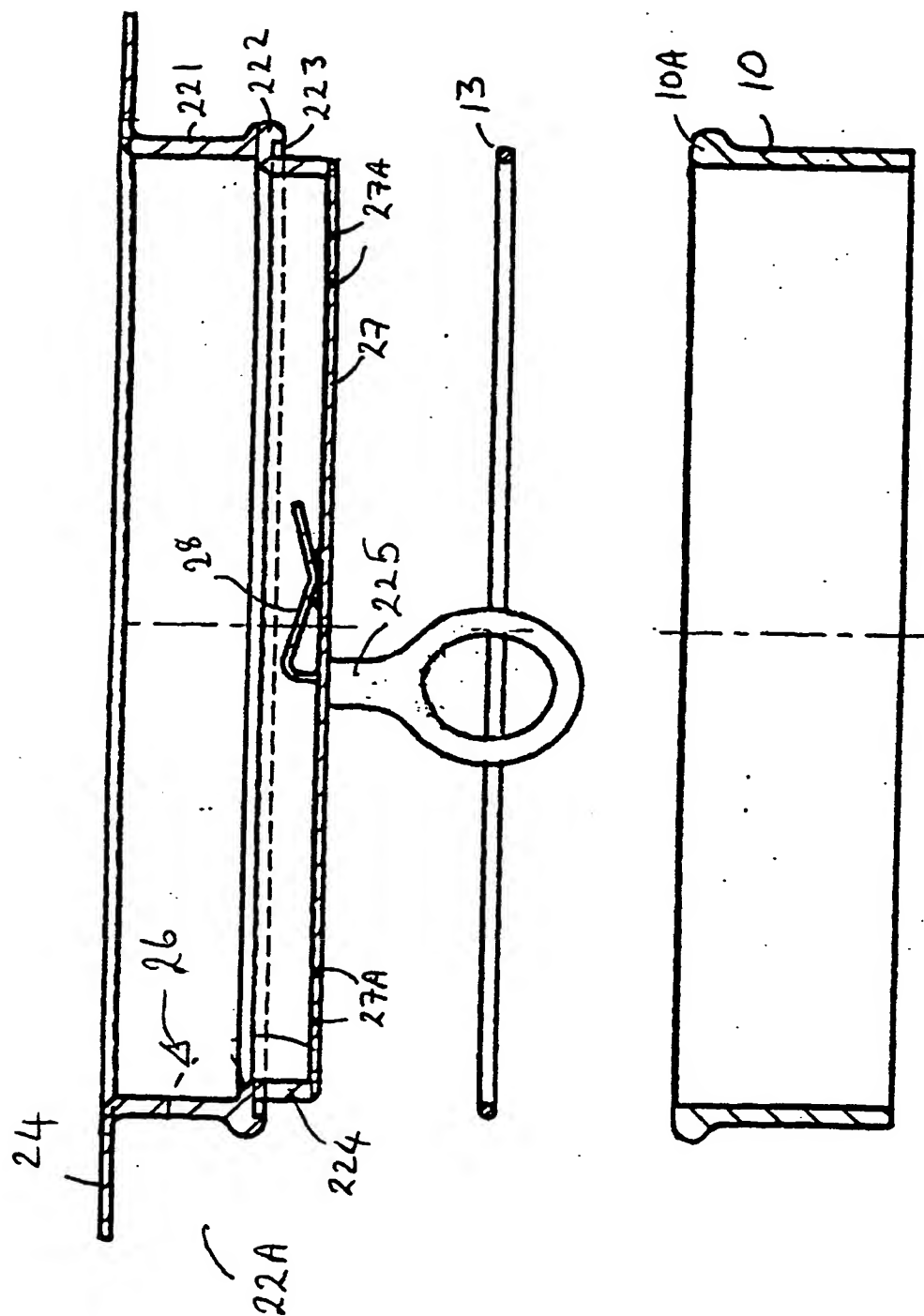
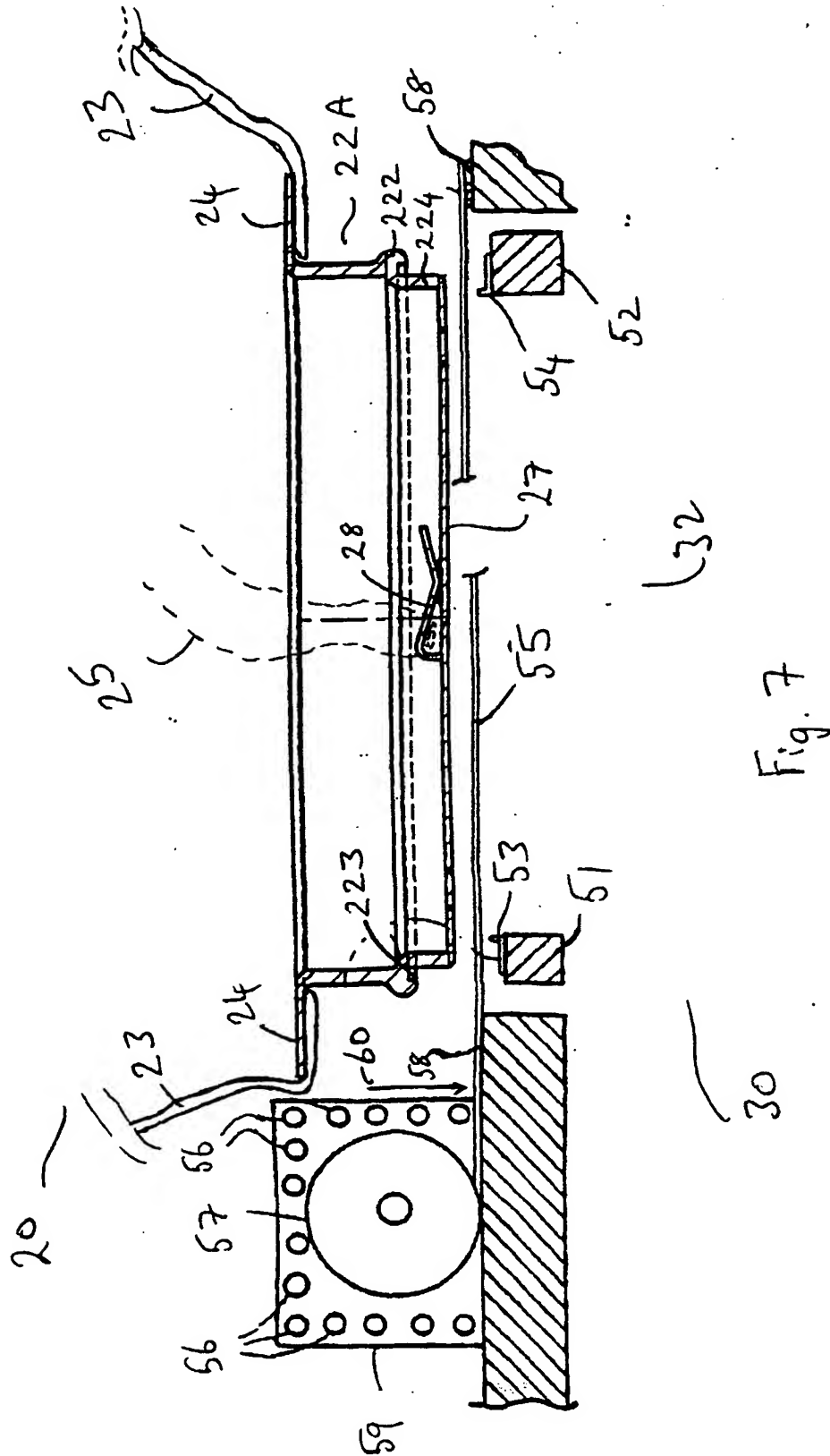


Fig. 6





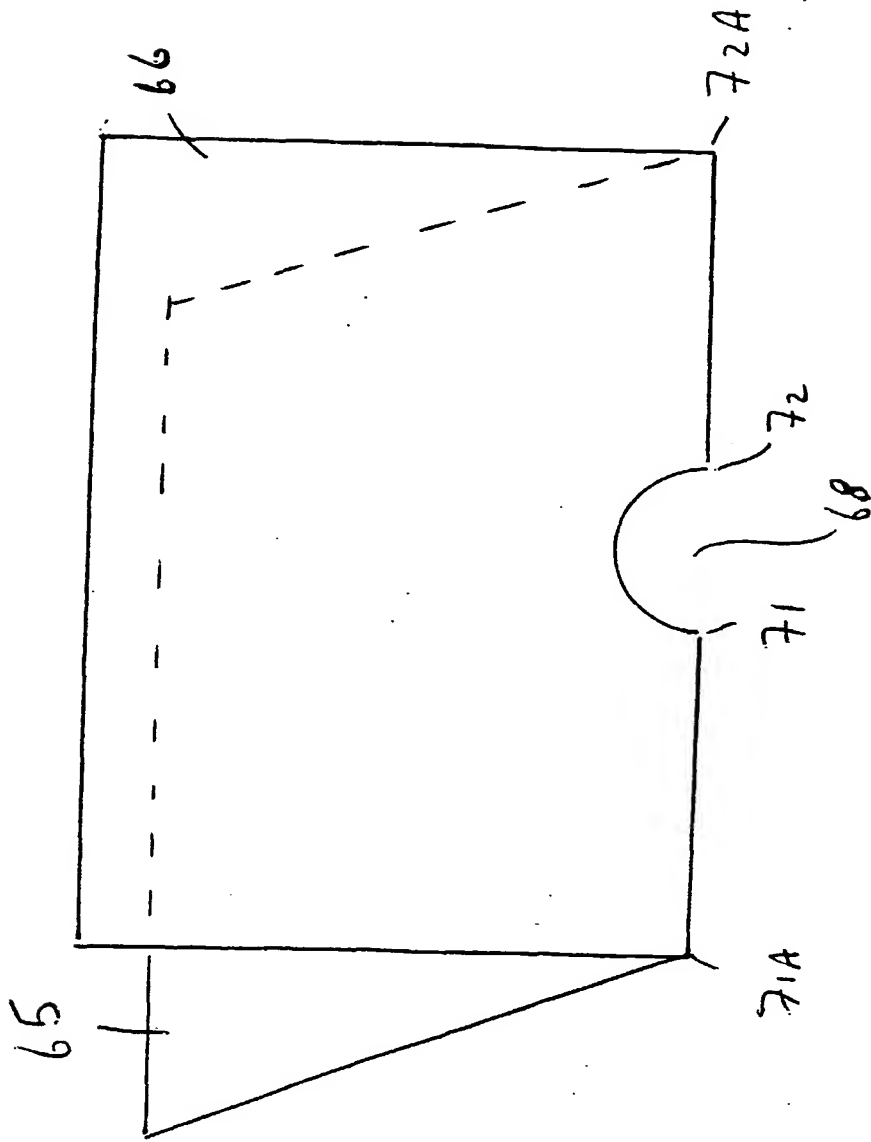


Fig. 8

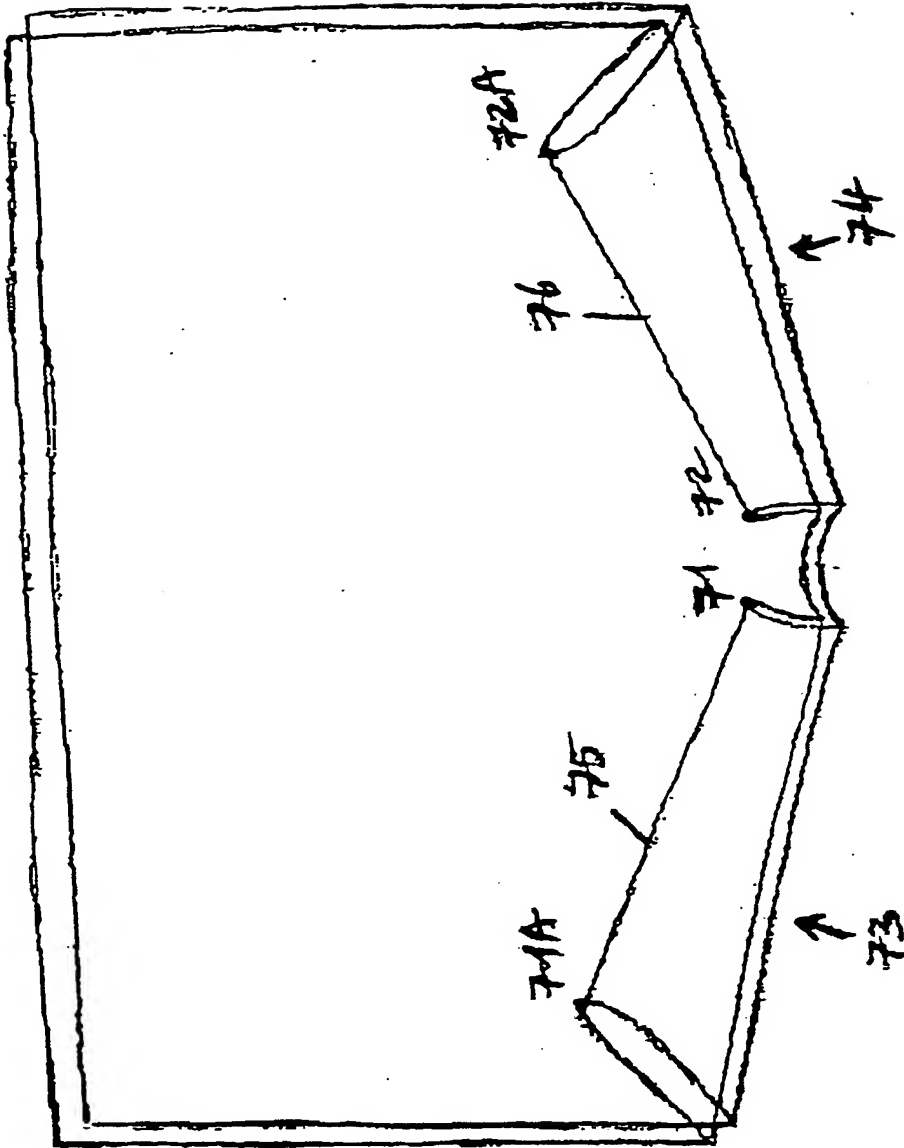


Fig. 9

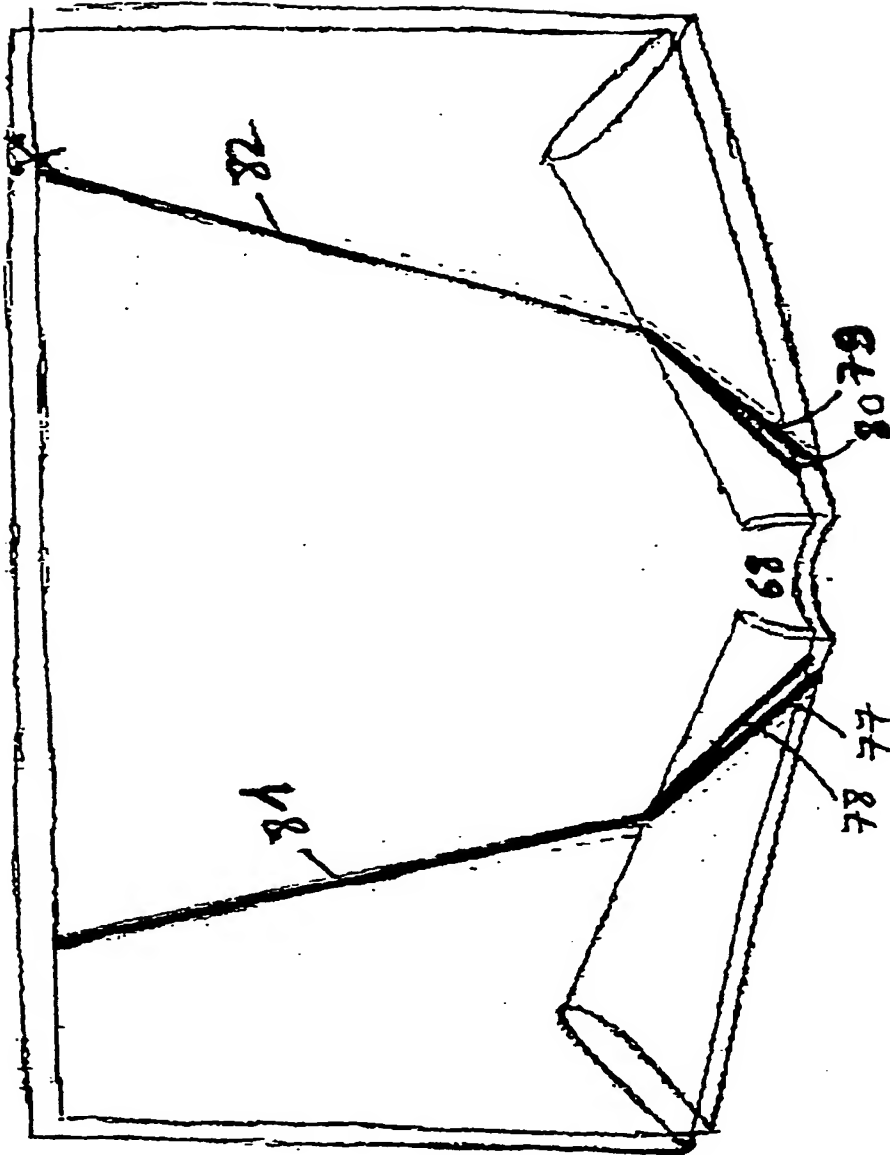
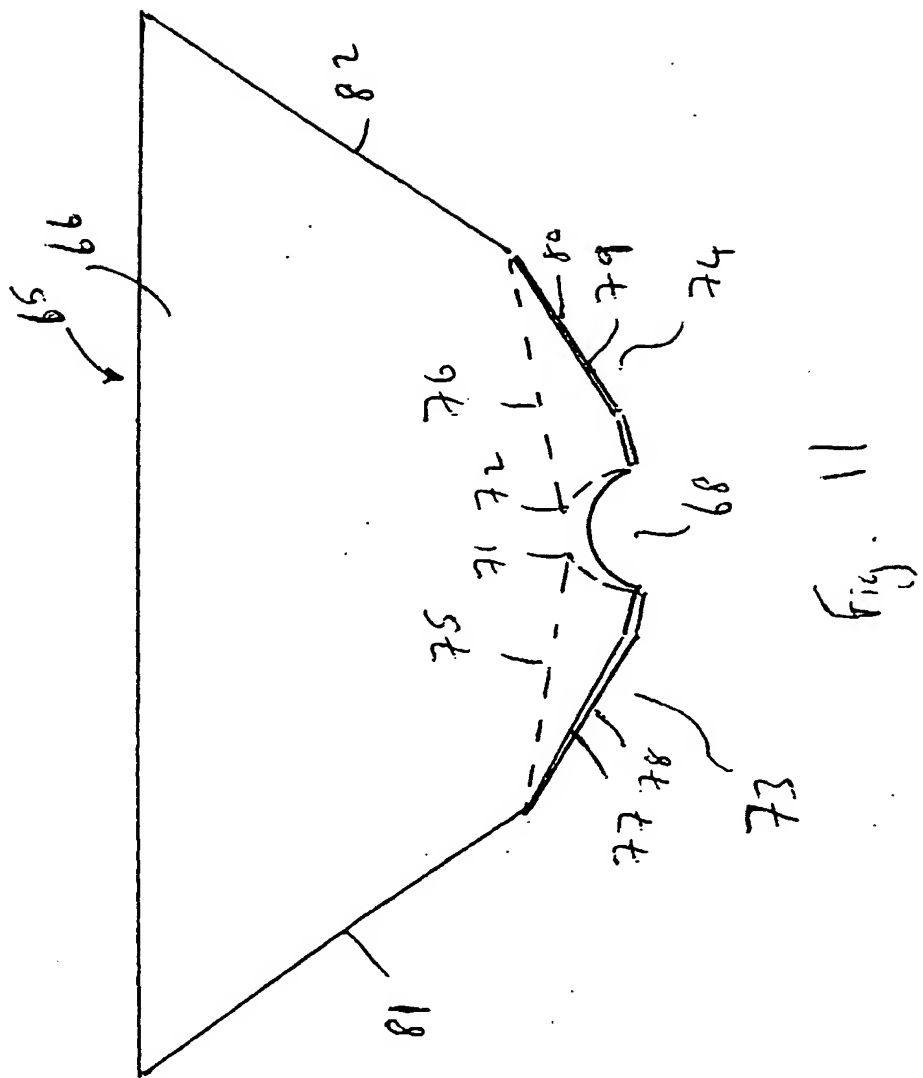
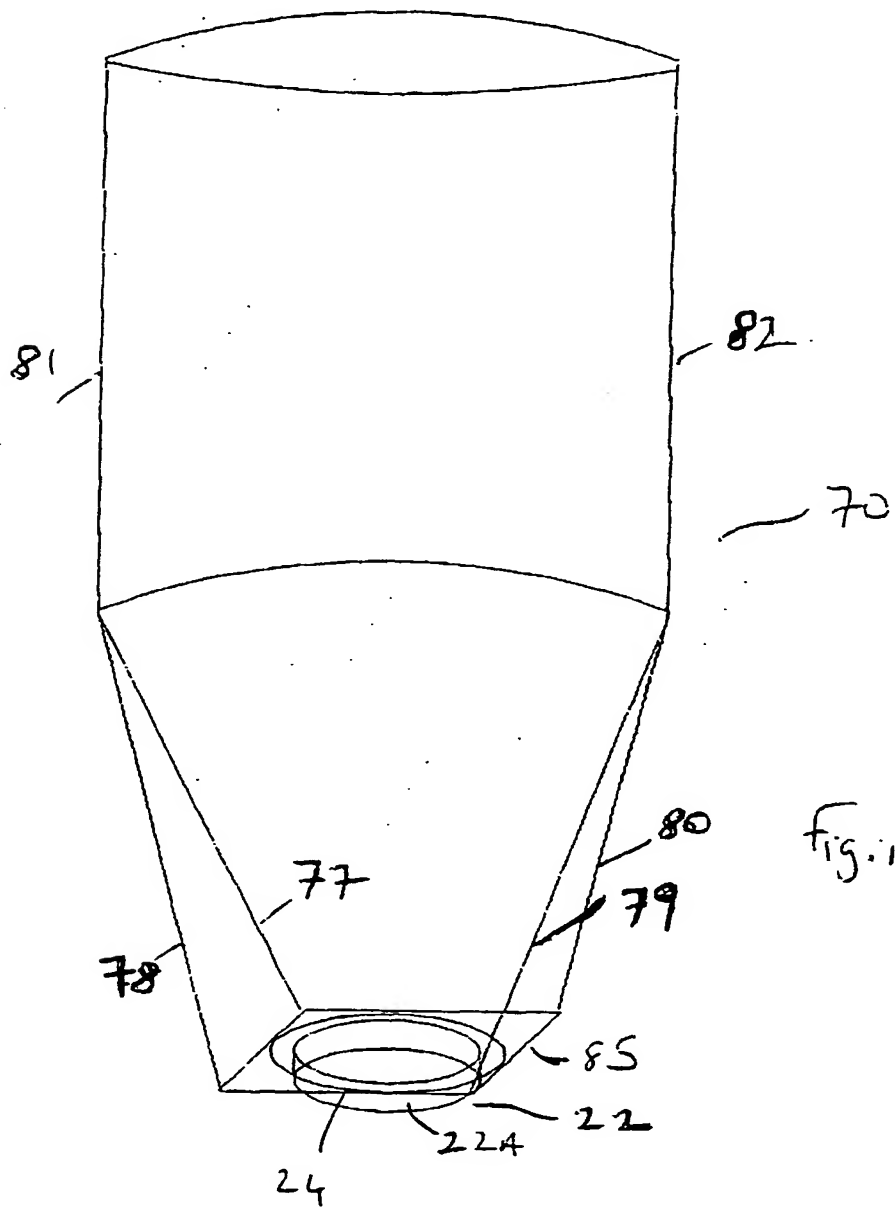
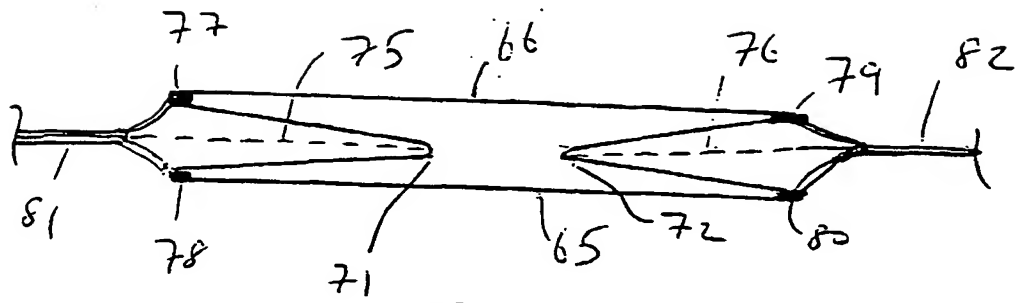
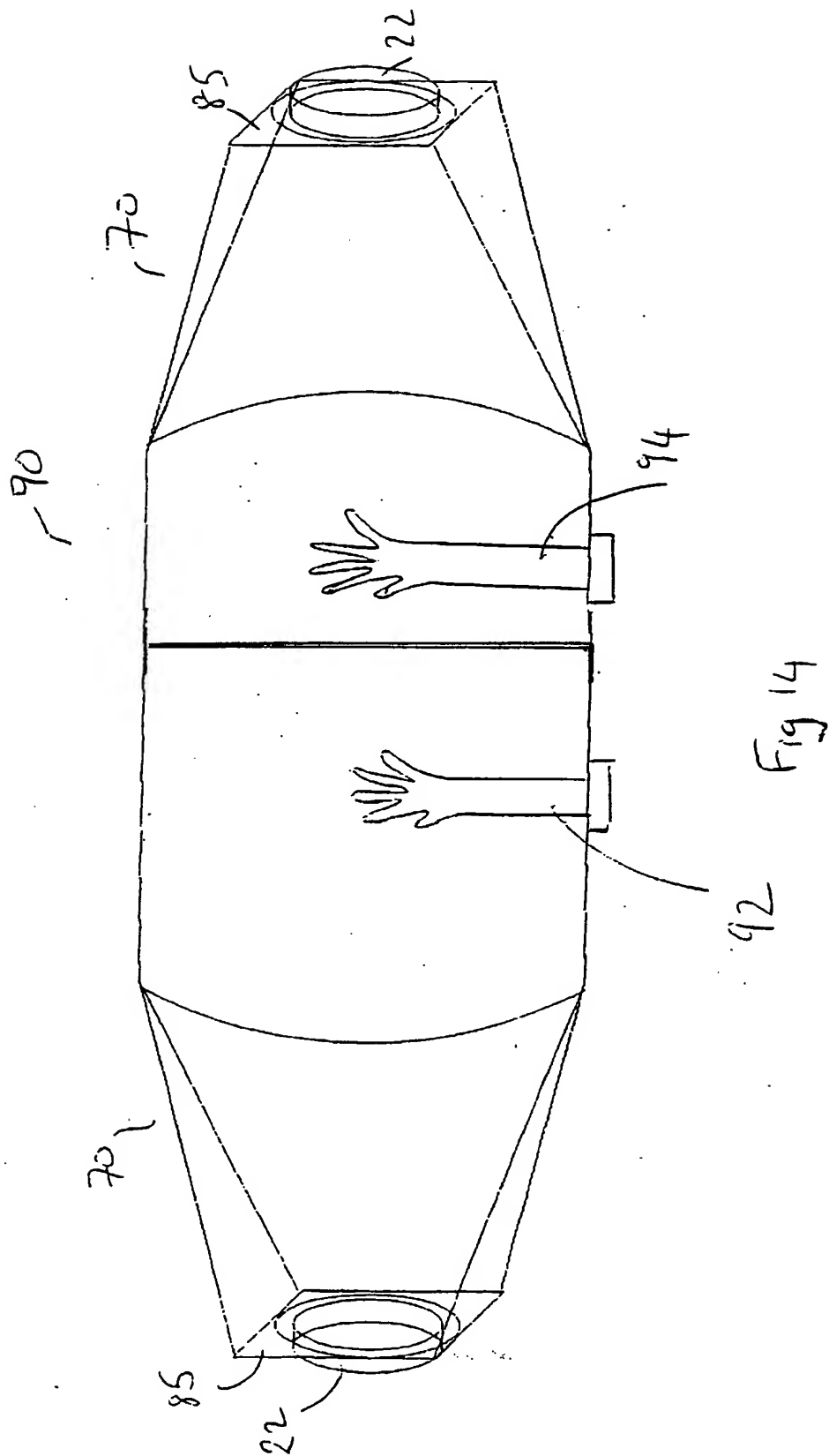


Fig. 10









European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number  
EP 99 20 3580

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
D, X	US 5 447 699 A (PAPCIAK CHARLES ET AL) 5 September 1995 (1995-09-05) * figure 1 *	1, 2, 4, 7, 11-15	A61L2/26
D, X	US 5 735 609 A (NORTON PAUL H) 7 April 1998 (1998-04-07) * the whole document *	1, 2, 4-6, 8, 11-15	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61L B65B
The present search report has been drawn up for all claims			
Place of search <b>THE HAGUE</b>		Date of completion of the search <b>4 February 2000</b>	Examiner <b>Heck, G</b>
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons  &amp; : member of the same patent family, corresponding document</p>			



**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 20 3580

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.  
The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

04-02-2000

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5447699	A	05-09-1995	NONE	
US 5735609	A	07-04-1998	AU 714122 B	16-12-1999
			AU 4040697 A	09-02-1998
			CA 2261112 A	22-01-1998
			WO 9802360 A	22-01-1998

EPO FORM P459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



CA

From the INTERNATIONAL SEARCHING AUTHORITY

**PCT**

To:

MILLIPORE CORPORATION  
Attn. Hubbard, John Dana  
290 Concord Road  
Billerica, MA 01821  
UNITED STATES OF AMERICA

**RECEIVED**

APR 23 2004

**LEGAL DEPT.**

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

20/04/2004

Applicant's or agent's file reference

MCA-616 PC

**FOR FURTHER ACTION**

See paragraphs 1 and 4 below

International application No.

PCT/US 03/28277

International filing date  
(day/month/year)

09/09/2003

Applicant

MILLIPORE CORPORATION

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Véronique Baillet

Docketed By: MC 4/23/04

Due Date:

Reminder(s):

Action Due:

In Database:

Arr 19 rem 5/20/04  
IDS rem 6/20/04  
Arr 19 due 6/20/04  
IDS due 7/20/04



These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

## INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

### What documents must/may accompany the amendments?

#### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**



The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

**The following examples illustrate the manner in which amendments must be explained in the accompanying letter:**

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

**"Statement under article 19(1)" (Rule 46.4)**

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

**It must be in the language in which the international application is to be published.**

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

**Consequence if a demand for international preliminary examination has already been filed**

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

**Consequence with regard to translation of the international application for entry into the national phase**

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

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